



BIS VIEW™ Monitoring System

SERVICE INFORMATION MANUAL

Aspect Medical Systems, Inc.

Bispectral Index™ (BIS™) Monitoring System

Rx only



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ABOUT THIS MANUAL

This manual contains information necessary for the customer to install, maintain, service, identify and prepare for use Aspect Medical Systems' BIS VIEW™ Monitoring System. Also included are directions to diagnose, troubleshoot, and repair the system. A spare parts and accessories list and system specifications are included.

This manual is intended to be used in combination with the BIS VIEW Monitoring System Operating Manual.

The BIS VIEW Monitoring System is designed and manufactured using state-of-the-art components and manufacturing processes. Field repair or customer repairs are therefore limited by design to replacement of major component assemblies such as the Patient Interface Cable (PIC), BISx™, the BIS VIEW monitor, or the monitor's power supply and battery.

This manual, in conjunction with the BIS VIEW Monitoring System Operating Manual, contains the maintenance and diagnostic troubleshooting information necessary for customer qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal components of the BIS VIEW monitor, with the exception of the power supply and battery.

Before attempting to set up or service the BIS VIEW Monitoring System, please familiarize yourself with the safety information provided in Section 1 of this manual.

Important Information about Using BIS Monitoring

The BIS VIEW Monitoring System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. The system, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, one of the BIS VIEW monitor's output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

BIS is a complex monitoring technology intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical signs. **Reliance on the BIS alone for intraoperative anesthetic management is not recommended.** As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. BIS values should also be interpreted cautiously with certain anesthetic combinations, such as those relying primarily on either ketamine or nitrous oxide/narcotics to produce unconsciousness. Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders and those taking other psychoactive medications.

The BIS education site, www.biseducation.com, offers relevant information and published articles on the clinical use of BIS. In addition, there is a “Monitoring Consciousness Using the Bispectral Index during Anesthesia” Clinician’s Pocket Guide available on the website and through your local Aspect Representative.

For more information, please contact Aspect Medical Systems at (800) 442-2051. If you require additional information on the use of BIS, please contact Aspect Medical Systems Clinical Support at 800-442-8655 or 617-559-7655 if calling from outside of the USA.

I SAFETY PRECAUTIONS

INTRODUCTION:

Caution:

Carefully read the BIS VIEW Monitoring System Operating Manual entirely before using the monitor in a clinical setting.

WARNINGS, CAUTIONS, AND NOTES

The terms warning, caution, and note have specific meanings in this manual.

- A **WARNING** advises against certain actions or situations that could result in personal injury or death.
- A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.
- A **NOTE** provides useful information regarding a function or procedure.

KEY TO SYMBOLS

A key to the symbols that may appear on the BIS VIEW Monitoring System appears at the end of this section.

I.1 Warnings

GROUND WIRE LEAKAGE CURRENT MUST BE CHECKED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN WHENEVER INSTRUMENT CASE IS OPENED.

EXPLOSION HAZARD: DO NOT USE THE BIS VIEW SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

USE ONLY THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT A NON-STANDARD OUTLET.

U.S.A. REQUIREMENT: FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VIEW SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS, INCLUDING THE NEUTRAL ELECTRODE, SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS IN THE HIGH-FREQUENCY SURGICAL NEUTRAL ELECTRODE CONNECTION, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

TO REDUCE THE HAZARD OF BURNS DURING USE OF BRAIN-STIMULATING DEVICES (e.g., TRANSCRANIAL ELECTRICAL MOTOR EVOKED POTENTIAL), PLACE STIMULATING ELECTRODES AS FAR AS POSSIBLE FROM THE BIS™ SENSOR AND MAKE CERTAIN THAT SENSOR IS PLACED ACCORDING TO PACKAGE INSTRUCTIONS.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE BIS VIEW SYSTEM.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST GROUND LEAKAGE CURRENT BEFORE FURTHER USE.

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL INJURY.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

DUE TO ELEVATED SURFACE TEMPERATURE, DO NOT PLACE BIS_x IN PROLONGED DIRECT CONTACT WITH PATIENT'S SKIN, AS IT MAY CAUSE DISCOMFORT.

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA), AS HAZARDOUS GASES MAY RESULT.

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-2-26 HARMONIZED NATIONAL STANDARD.**

POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VIEW POWER SUPPLY.

I.2 Cautions

Read this entire manual carefully before using the monitor in a clinical setting.

To completely remove power from the unit: put the monitor in standby mode, disconnect power cord from the power cord receptacle of the monitor, then remove the battery from the monitor.

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment (e.g., evoked potential monitors).

Do not autoclave the BIS_x or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connector can interfere with PIC performance.

Considerations when using Electro-Convulsive Therapy (ECT) equipment during BIS monitoring: Place ECT electrodes as far as possible from the BIS sensor to minimize the effect of interference. Certain ECT equipment may interfere with the proper function of the BIS monitoring system. Check for compatibility of equipment during patient setup.

Check the battery periodically by operating a BIS VIEW monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage, charge the battery for 6 hours to assure full capacity. If the BIS VIEW monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VIEW monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery, P/N 186-0208.

All repairs to the BIS VIEW Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

Use only the parts and tools specified. Use of any others may damage the instrument.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VIEW Monitoring System.

The BIS VIEW Monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VIEW monitor should be observed to verify normal operation in the configuration in which it will be used.

Do not block ventilation inlet holes on the underside of monitor.

Do not open the BISx. The seal to prevent liquids from entering the BISx may be damaged if opened. Service or repairs must be performed only by qualified biomedical technicians.

The BIS VIEW system has been designed to operate with a BIS Sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep™ technology and uses a proprietary connector. Use of other electrodes is not recommended.

Do not disconnect the BISx during a BISx software upgrade.

The BIS VIEW system complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- Increase separation between devices
- Re-orient device cabling
- Plug devices into separate outlet circuit branches

Refer to Section 9.2 “Electromagnetic Compatibility Specifications.”

When connecting or disconnecting BISx, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

All work involving opening the instrument case must be performed in a static-safe environment to prevent damage to electronic components and assemblies. This environment includes the operator, work area and tools, and any other test or storage items that might touch the monitor or BISx assemblies.

Exposed metal parts are double insulated from live parts of the monitor and are not wired for safety current. A ground continuity test is not recommended.

Important:

The BIS VIEW systems comply with the European Medical Device Directive (MDD) and applicable regulatory requirements of the country distributed to and carry the CE_{xxxx} Marking. Declarations of Conformity provided upon request where appropriate.

I.3 Key to Symbols































	Caution: Consult Accompanying Documents		Data I/O, RS-232 Serial Port
USB-A	Universal Serial Bus: Type A	USB-B	Universal Serial Bus: Type B
	Caution: Hot Surface		Storage Temperature Limits
	Type BF Equipment		Type BF Equipment Defibrillator-proof
	Alternating Current (A/C)		Direct Current (D/C)
	Battery Location		Reset Button
	Monitor Power ON		Monitor Power OFF or Standby Mode
	Do not Reuse		Use by YYYY-MM-DD or YYYY-MM
	Latex-free product		PVC-free product
	Manufacturer		Date of Manufacture
	Authorized Representative in the European Community		Catalog Number
	Batch Code		Serial Number
	Conformité Européenne (CE) Marking of Conformity to European Medical Device Directive. CEXXXX represents the Notified Body number		Classified by Underwriters Laboratories Inc.® with respect to electric shock, fire and mechanical hazards only, in accordance with UL 60601-1 and IEC60601-2-26
	Recognized under the Component Recognition Program of Underwriters Laboratories Inc.		Packaging Labeling: Fragile, Do Not Get Wet, and This Side Up

Figure 1 - Symbol Key (page 1 of 3)

	Recyclable		Crossed out wheellie bin indicates separate treatment from general waste at end of life *
	Product marked with a number contains certain toxic or hazardous substances or elements, and can be used safely during its Environment-Friendly Use Period (EFUP). The product should be recycled. The Environment-Friendly Use Period is valid only when the product is operated under the conditions defined in the product manual. **		Product marked with the “e” does not contain any toxic or hazardous substances or elements, and is green and environmental. The product can be recycled. **

*Contact Aspect Medical Systems International B.V. for a Return Materials Authorization (RMA) number or contact your municipality or the nearest collection site to dispose of waste equipment. According to the WEEE Directive 2002/96/EC, all waste electrical and electronic equipment (EEE) should be disposed of and collected separately and treated according to the best available and environmentally friendly techniques.

EEE contains hazardous substances to the (human) environment but also EEE is a valuable resource of new raw materials. Therefore it is important to collect WEEE separately from other waste.

Aspect Medical products are subject to the Directive and we therefore urge you to dispose of the equipment separately from ‘normal’ household waste and make sure that it is treated at an electronics recycler.

** Refer to www.aspectmedical.com for Material Declaration Data Sheets.

Figure 1 - Symbol Key (page 2 of 3)

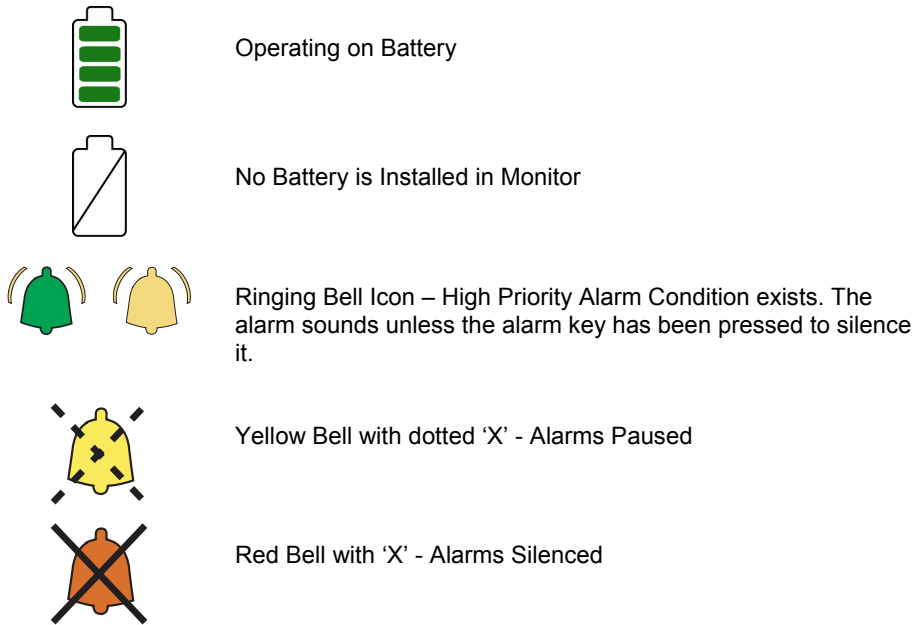


Figure 1 - Symbol Key (page 3 of 3)

2 BIS VIEW MONITORING SYSTEM OVERVIEW

2.1 Introducing the BIS VIEW Monitoring System

The BIS VIEW Monitoring System processes raw EEG signals to produce a single number, called the Bispectral Index™, or BIS, which correlates to the patient's level of hypnosis. It operates from an AC power source of 100V to 240V, 50/60Hz, and provides approximately 45 minutes of automatic back-up battery power.

The monitor is menu-driven. A detailed description of how the BIS VIEW Monitoring System works is included in the BIS VIEW Operating Manual. Please refer to the BIS VIEW Operating Manual for additional information.

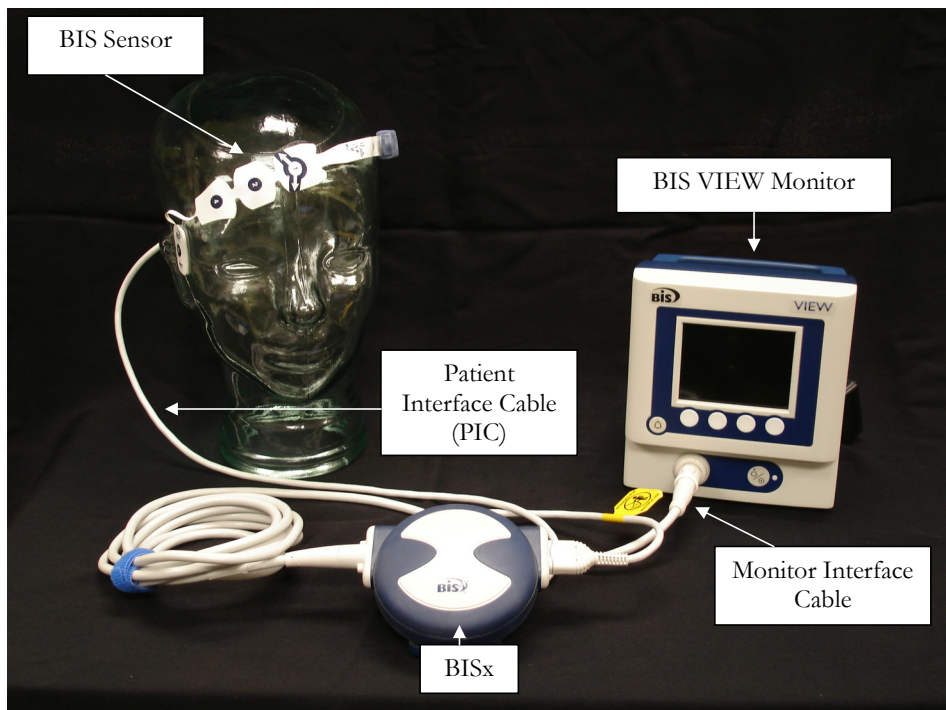


Figure 2- The BIS VIEW Monitoring System

2.2 Principal Components

The system is composed of a monitor, a BISx, a Patient Interface Cable (PIC), and BIS sensor.

2.2.1 The BIS VIEW Monitor

The front panel of the BIS VIEW monitor contains four soft keys, an alarm key, the BISx port and the ON/Standby button. See Figure 2.

Soft Keys

The four white “soft” keys directly under the BIS VIEW screen are used to make all selections. These keys are designed to function even when the user is wearing examination gloves.

Alarm Key



The Alarm Key is used to pause, silence, or reinstate audible alarms.

ON/Standby button



The ON/Standby button is located in the lower right corner of the monitor and is used to put the monitor in ON or in Standby mode. When the small LED light to the right of the ON/Standby button is green, the unit is running and providing power to the BISx. When it is yellow, the battery is charging and the system is in Standby mode. When it is not lit, no A/C power is available to the unit; pressing the ON/Standby button will start up the monitor using the battery.

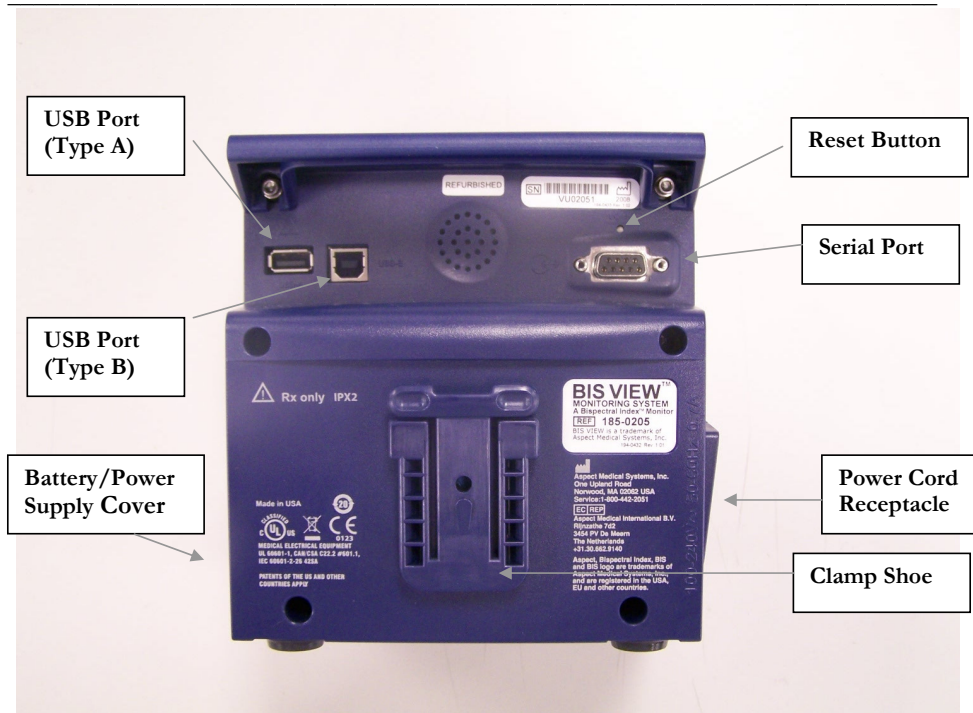


Figure 3 - Rear Panel

Rear Panel

The rear panel components are pictured in Figure 3. They include: two USB ports (Type A and B), the clamp shoe, an RS-232 port, the Reset button, the Battery/Power Supply cover, and the power cord receptacle.

The clamp shoe allows the monitor to slide into the pole clamp so that it can be attached to a $\frac{1}{2}$ " – $1\frac{1}{2}$ " diameter vertical pole.

2.2.2 The BISx and Patient Interface Cable (PIC)

The BISx receives, filters, and processes patient EEG signals. It is located close to the patient's head where the EEG signal is less subject to interference from other medical equipment.



Figure 4 - The BISx and PIC

The BISx is shown in Figure 4. Its long flexible **Monitor Interface Cable** connects to the front of the monitor. The **Patient Interface Cable (PIC)** connects the BIS sensor to the BISx.

The attachment clip on the BISx is used to secure it in a convenient location near the patient's head.

2.3 Instrument Identification

BIS VIEW Monitor

Monitor identification information is permanently marked on the rear panel. This information includes instrument model and serial numbers, power ratings, cautions, and the Aspect Medical Systems shipping address.

BISx

The BISx identification information is permanently marked on its rear panel. This information includes instrument model and serial numbers and cautions.

PIC

The Patient Interface Cable lot number is stamped on the cable itself.

Software Revision Numbers

Software revision numbers may be displayed by selecting **[System Configuration]** from the **Diagnostics** Menu.

2.4 Proprietary Information and Devices

Information and descriptions contained in this guide are the property of Aspect Medical Systems and may not be copied, reproduced or distributed without prior written permission. Portions of the BIS VIEW Monitoring System design are proprietary and are the subject of patents and patents pending. See the BIS VIEW Operating Manual for details.

3 PRINCIPLES OF OPERATION

INTRODUCTION

This section includes:

- How the BIS VIEW Monitoring System works
- The architecture of the BIS VIEW monitor and BISx
- System Features

3.1 How the BIS VIEW Monitoring System Works

The BIS VIEW Monitoring System consists of:

- The BIS monitor with built-in battery backup and detachable power cord
- The BISx
- Aspect's Patient Interface Cable (PIC) and BIS sensor.

A sensor placed on the patient's head transmits EEG signals to the BISx. The BISx filters the data, analyzes it for artifact and processes it using digital signal processing techniques, then sends the data to the monitor for display. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.

3.2 System Architecture

Hardware is divided into three main components: the monitor, the BISx, and the Patient Interface Cable (PIC) with BIS sensor. The BISx contains the circuits that acquire and digitize the EEG signals, digitally process the EEG data, and compute the processed parameters. The BIS VIEW monitor contains the circuits to display the waveforms and processed parameters. The PIC and BIS sensor are the patient connection for EEG signal acquisition.

A block diagram depicting the monitor subassemblies appears in Figure 5. A data flow diagram appears in Figure 6.

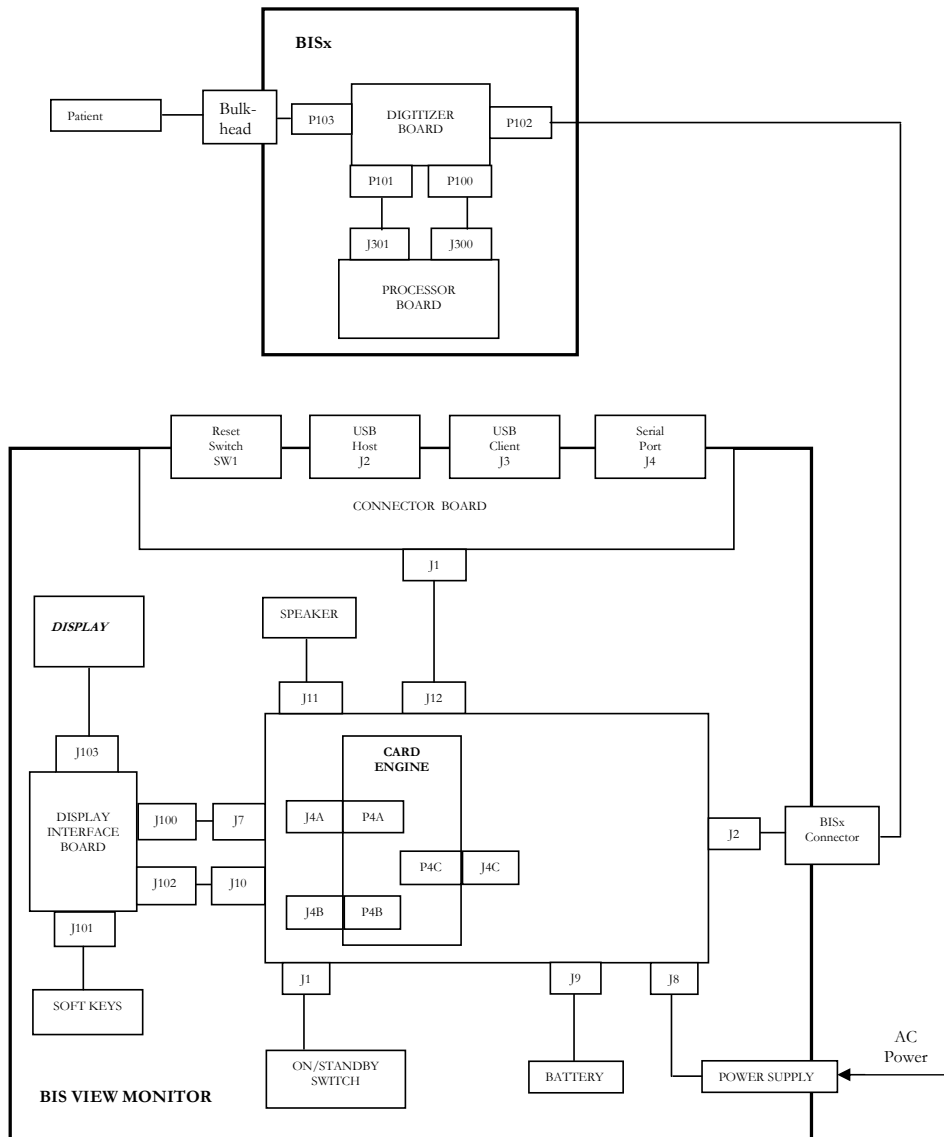


Figure 5 - The BIS VIEW System Block Diagram

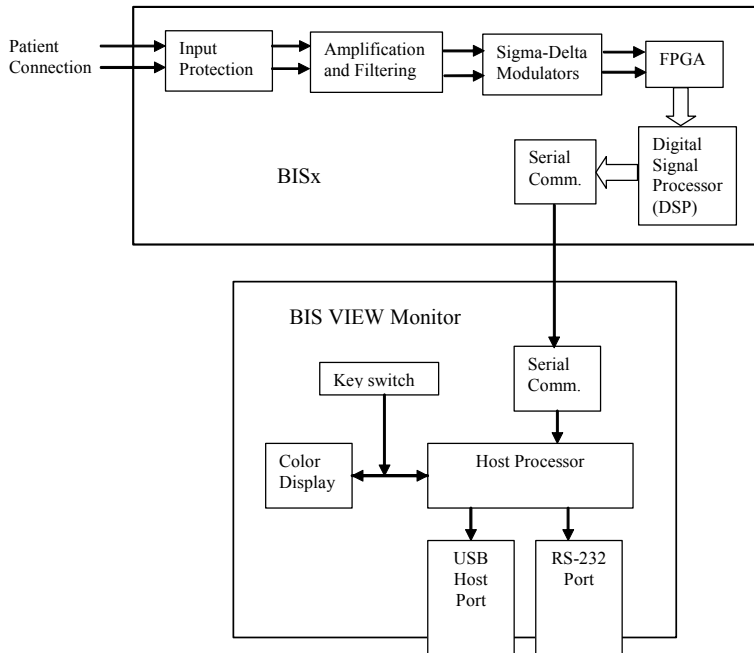


Figure 6 - The BIS VIEW Data Flow Diagram

After passing through input protection circuits, the EEG signals are differentially amplified and filtered to remove DC and high frequency components. The signals are digitized by separate one bit sigma-delta analog to digital converters and sent to the Digital Signal Processor (DSP). The DSP filters the signals and computes the processed variables. The results are passed to the monitor for display.

3.2.1 The BISx

The BISx contains the inputs, amplifiers, and digitizers for two channels of EEG, and contains the circuits to digitally process the EEG data and compute the processed parameters. It has a single point connection that connects via a Patient Interface Cable (PIC) to a BIS sensor. The sensor and PIC contain circuits for identifying them to the monitor. This permits the monitor to configure automatically.

The BISx acquires and processes the EEG signals and also contains circuits for injecting self-test voltages into the amplifier inputs. It constantly monitors the combined source impedance from the sensor electrodes and is able to measure the individual impedance of

the channel and ground electrodes and detect if an electrode is disconnected. The BISx provides the patient isolation barrier that isolates the patient from the monitor electronics.

3.2.1.1 BISx Signal Conditioning

The input protection circuits are designed to protect the input from damage by electric shock from sources such as electrostatic discharge (ESD) or defibrillation. The protection circuits also reduce the effects of high frequency ambient noise from sources such as electrocautery and other devices.

Input signals are amplified by instrumentation amplifiers, which have a fixed gain. The amplifiers have DC servos, which remove the signals below high pass cutoff frequency. In the event of amplifier overload, the servos are changed to a faster response time to facilitate fast recovery (blocking) under control of the host processor.

Each channel is further amplified to the level required by the A/D converters. The amplifiers also serve as filters to prevent aliasing by the converters.

3.2.1.2 BISx Impedance Testing

In the default state of the BISx the combined channel electrodes' impedance is continuously checked. A small current (approximately 1 nanoampere) is injected into each electrode at 128 Hz, just above the EEG band. The resulting voltages are measured. Equal but opposite currents are injected into the (+) and (-) electrodes simultaneously while the digital signal processor measures the resulting voltage. BIS monitoring is performed while combined impedance is checked.

The BISx measures the individual electrode impedance during a sensor check by injecting current into the REF electrode only. Individual electrode impedance is derived by subtracting the resulting value from the combined value.

The ground electrode impedance is also measured while injecting current into the REF electrode. BIS monitoring is interrupted while the ground impedance is checked. Ground impedance checking occurs when a sensor check is performed and thereafter on a 10-minute schedule during patient monitoring.

The impedance check signal can occasionally interfere with other monitoring equipment connected to the patient. Evoked potential monitors are particularly susceptible because they use a wide bandwidth. The automatic impedance check feature can be turned off by selecting "Impedance Checking – OFF" in the **Diagnostics** menu. (See Operating Manual for specific instructions).

3.2.1.3 BISx Processor and Communications Circuits

The BISx contains: an analog to digital (A/D) converter for each channel, the monitor interface, the sensor interface and the power supply circuits. A crystal controlled BISx master clock is on this board. This clock is the system's BIS processing clock.

A/D Conversion

There are two independent sigma-delta modulators for the two channels. These run at 16384 samples per second.

Output from the two channels is multiplexed in a field programmable gate array (FPGA). Multiplexed with the EEG data is status information such as BISx identification, “lead off” indication, and power supply faults.

Ground Fault Monitor

Patient auxiliary current from a single electrical fault must be limited to 50 uA (as required by the safety standard, IEC 60601-1). A single fault current will always return through the patient ground lead because all other inputs are high impedance. The ground fault monitor therefore monitors the current in the ground lead.

The circuit is designed to measure either positive or negative currents in excess of 50 uA. Faults lasting for a period of 2 seconds are flagged and cause the isolated analog supply to shut down. Additional circuitry prevents false triggering due to excessive noise such as those generated by electro-surgery.

Smart Chip Functions

The smart chip is an integrated circuit embedded in the sensor. It is used for sensor authentication and to keep track of the number of times the sensor is used. The communication between the BISx and the smart chip is initiated when the BISx detects the presence of the smart chip. After the data is read, it is discontinued during the monitoring process to prevent interference with the EEG signal. If the current exceeds 25 mA, it is assumed there is something wrong with the smart chip and power to the chip is switched off.

Cautery Detector

The cautery detector detects the common mode current passing through the sensor and out through the transformer capacitance. It can detect large differential lead voltages also. The electro-cautery detection circuit is connected to the Channel 1 – lead, as this is the farthest lead from the ground lead. As cautery energy has frequency content in the 100 - 500 KHz range, the detector senses only signals above 20 KHz and will send out a cautery detect signal when these signals exceed 20 uA.

Test Signal

A calibrated test signal is generated during the DSC Self Test. The signal is a 2 Hz square wave of approximately $\pm 50\mu\text{V}$. It is applied to the inputs of the differential amplifiers, resulting in a test of the entire signal path except for the input connections and protection circuits. During the Self Test, noise, gain and frequency response are checked.

Interface to the Monitor

The BISx uses an RS-232 interface to communicate with the VIEW monitor. Control commands are received from the monitor and acknowledged by BISx and BISx transmits data and status information to the monitor. The Monitor Interface Cable also supplies power to the BISx and includes a circuit that allows the monitor to detect connection of the BISx.

BISx Power Supply (Patented technology)

The BISx derives power from the monitor. Power supply circuitry produces the necessary voltages for operation. Power for patient-connected circuits is provided through an isolation transformer. These circuits are isolated for patient safety.

3.2.1.4 The BISx Mechanicals

The BISx is contained in a small custom designed plastic case (see Figure 4). It is connected to the monitor via the Monitor Interface Cable and connects to the BIS sensor via the Patient Interface Cable (PIC). Both cables are strain relieved. The cables and the BISx Bulkhead Connector (used to attach the PIC to the BISx) can be replaced, if necessary, by a qualified biomedical engineering technician. The attachment clip on the back of the BISx may be used to secure it to a convenient location near the patient's head.

There are no ventilation holes in the BISx case. It will not leak when splashed with liquids. The case is electrically shielded both to prevent spurious emissions from the BISx and to prevent externally caused interference with the BISx circuits.

3.2.2 The BIS VIEW Monitor

The BIS VIEW monitor contains the circuits to enable the soft keys, to receive processed parameters from the BISx, to display the data on the screen, and to communicate with other devices via USB and RS-232 ports.

The monitor also contains the circuits for powering the monitor and the BISx. An on board annunciator generates alarm sounds.

A block diagram depicting the monitor subassemblies appears in Figure 5. A data flow diagram appears in Figure 6. The signals are acquired, digitized, filtered, and processed by the BISx. The BISx multiplexes the signals onto the BISx communications line. The data are de-multiplexed in the monitor for display.

The Main board, with the card engine, controls all inputs and outputs, power, data memory, and clock functions. The Card Engine also controls the screen display, the internal power supplies, the monitor data communications and general sequencing of the internal computer and power supplies.

The Connector board connects the reset button, USB and serial ports to the main board. There are two USB ports. The USB Type A port is used to export data to a removable drive. It is also used to upgrade monitor and BISx software. The USB (Type B) port is for manufacturer's use only. The RS-232 serial port can be used to transfer data from the monitor.

All exposed metal parts on the rear of the BIS VISTA monitor are separated from live parts by double insulation. Although some metal parts may be wired to carry functional current to earth ground, they are not wired for safety current. Therefore a ground continuity test is not recommended.

Caution:

Exposed metal parts are double insulated from live parts of the monitor and are not wired for safety current. A ground continuity test is not recommended.

3.2.2.1 The BISx Interface

The BISx interface is composed of two RS-232 serial lines, one going to the BISx and another bringing data from the BISx, plus a 5 volt line for powering the BISx.

The 5 volt power to the interface is under software control.

3.2.2.2 The Interconnect Board

The Interconnect board provides the physical mounting and electrical connections for the serial and USB ports. Its mechanical construction includes ESD protection.

3.2.2.3 The Power Supply

The BIS VIEW utilizes a commercial Class I medical-grade power supply which operates on AC power from 100-240 VAC, 50-60 Hz, with output of 12 VDC, 24 watt maximum. It charges the battery; 7.2 V (nominal), 2150 mA hr. The power supply contains internal fuses that are not user accessible.

Signals from the motherboard are provided to the processor to indicate A.C. or battery powered, and low battery.

Caution:

**To turn off all A/C power, disconnect power cord from A/C outlet.
Battery can be removed to shut down unit completely.**

3.2.2.4 The Battery

The battery is for backup use only. The battery includes temperature and current control elements, and has a nominal output of 7.2 volts DC. The battery charges whenever the BIS VIEW monitor is plugged into A/C power. It is capable of supporting monitor operation for approximately 45 minutes.

Note:

The BIS VIEW monitor may not power up entirely if battery power is low. If that should occur, connect unit to wall power and press the Reset button. (Refer to Section 8.9 “Using the Reset Button.”)

3.3 System Features**3.3.1 System Self Checks**

The BIS VIEW monitor has several self-checking features to ensure that the system is operating properly. These include:

3.3.1.1 System Check

Software image checksums and trend data memory are tested and repaired if necessary: These tests are performed when the system is powered up for the first time, after a new battery or power supply are installed, or after the system has been reset.

3.3.1.2 Equipment and Connection Checks

The system checks continuously to be sure that the BISx, the PIC, and patient sensors are operating properly and have not become disconnected.

3.3.1.3 DSC Self Test

The DSC Self Test tests the digital signal acquisition and conversion functions of the BISx. It is a thorough test of the entire signal processing chain. The DSC Self Test may be initiated from the **Advanced Diagnostics** menu (See Section 6.3.2., “The BISx Checkout Procedure”)

3.3.1.4 Sensor Integrity Check

This test begins each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use.

3.3.1.5 Impedance Check (Sensor Check)

Electrode impedance is tested when the BISx, PIC and sensor are connected and is monitored continuously unless the user has turned impedance checking off in the menu system.

Caution:

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment, e.g., evoked potential monitors.

3.3.2 Diagnostic Codes

The BIS VIEW monitor provides diagnostic codes that may be helpful in tracing the source of particular signal characteristics caused by artifact or by unusual hardware or software conditions. Codes are displayed in the Message Region only if the user has requested them in the **Diagnostics** Menu.

3.3.3 Monitor Data Memory

The monitor stores recorded trend data with time and date of acquisition. The duration of trend data stored is approximately 72 hours.

When the memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the battery has been discharged and remains when the monitor is in the power off condition.

3.3.4 BISx Data Memory

The BISx stores processed EEG parameters, including the BIS value, with time and date of acquisition. History data stored in the BISx can be accessed by exporting it to a removable drive using the **[Export Data]** function. The duration of BISx data stored is approximately 1200 hours.

To view BISx history for a specific case, the user must first identify which BISx was in use during the case by looking up the BISx serial number in the **Advanced Diagnostics** menu's **[BISx Connection History]**. The appropriate serial number BISx can then be connected to any monitor to export its History Data.

When the BISx memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the monitor battery has been discharged and remains when the monitor and BISx are powered off.

3.3.5 Saved Settings

Whenever the monitor is started up from Standby mode, it reverts to user settings that have been set up and then saved using the **[SAVE ACTIVE]** selection from the **Settings** menu.

Note:

The **[SAVE ACTIVE]** option is disabled when in Battery Backup-Low Power condition. The following settings are not saved by the **[SAVE ACTIVE]** option: Impedance Checking (always returns to ON), Diagnostics Codes (returns to OFF).

To restore factory settings, go to **MENU/Maintenance/Default Settings** and press **[Restore]**.

3.3.6 Battery Operation

In the event of a power failure or interruption of power during a procedure, the monitor automatically switches to back-up battery operation. A fully charged battery will provide approximately 45 minutes of operation. When the system is running on battery, a battery icon displays next to the BIS number, indicating the battery status. When the battery reaches a low power condition, the monitor beeps and the battery symbol displayed on the screen changes color from green to orange. In addition, a "Battery Power Low" message blinks continuously in the Message area of the screen.

The Save Settings feature is disabled when the battery power is low. Battery recharge time is approximately 6 hours.

Caution:

**To turn off all A/C power, disconnect power cord from A/C outlet.
Battery can be removed to shut down unit completely.**

3.3.7 Data Transfer and Software Updates

Three ports on the rear of the BIS VIEW monitor facilitate data transfer. The USB (Type A) port is used to export data to a removable drive. It is also used to update the monitor and BISx software. The USB (Type B) port is for the manufacturer's use only.

BIS values and other EEG data may also be acquired from the monitor using the RS-232 serial port. To connect to a personal computer, please contact Aspect Medical Systems Technical Service for instructions. (See back cover for contact information.)

WARNINGS

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-2-26 HARMONIZED NATIONAL STANDARD.**

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1 LIMIT.

NOTE:

When software is updated, all previously recorded data and monitor configuration settings will be lost. Therefore, configuration settings should be recorded before the software update is performed.

4 PREPARATION FOR USE AND INSTALLATION

INTRODUCTION

This section provides an overview of installation information for service personnel working with the Aspect BIS VIEW Monitoring System. Please see the BIS VIEW Monitoring System Operating Manual for full installation instructions.

- Environment
- Instrument connections
- Installation and verification procedure

4.1 Environment

4.1.1 Shipping and Storage Environment

The monitor and its accessories can be stored or shipped within the following environmental limits. Note that these limits apply to non-operational storage and shipping situations.

Temperature	-10°C to +60°C
Humidity	15% to 95% (non-condensing)
Pressure	800 mm Hg (1500 feet below sea level) to 360mm Hg (20,000 feet above sea level)

Protect the monitor from sudden temperature changes that can lead to condensation within the instrument. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in the unopened shipping container at the inside ambient temperature before unpacking and placing into service. Before operation, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

4.1.2 Operating Environment

The BIS VIEW Monitoring System is not designed for use in areas containing flammable gases or vapors.

WARNING:

EXPLOSION HAZARD: DO NOT USE THE BIS VIEW SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

The BIS VIEW monitor is designed to operate safely under the following conditions. Conditions outside these ranges could affect reliability.

Temperature	0°C to +40°C
Humidity	15% to 95% (non-condensing)
Pressure	800 mm Hg (1500 feet below sea level) to 360mm Hg (20,000 feet above sea level)

4.1.3 Power Requirements and System Grounding

The BIS VIEW Monitoring System requires a power source of 100-240 VAC, 50-60Hz. Current consumption is 0.7 ampere maximum.

To protect operating personnel and patients, the monitor must be properly grounded. Accordingly, the monitor is equipped with a hospital grade line cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire receptacle.

WARNING!

USE ONLY THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT A NON-STANDARD OUTLET.

U.S.A. REQUIREMENT: FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VIEW MONITOR SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

4.1.4 Site Preparation: Mounting the Monitor

Aspect Medical Systems, Inc. strongly recommends permanent mounting of the BIS VIEW monitor to the anesthesia machine to enhance safety and facilitate ease-of-use. Please contact your local representative or Aspect to discuss mounting options.

WARNING!

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

4.1.4.1 Mounting the Monitor using the Pole Clamp

To mount the monitor to a secure vertical pole (1/2" - 1½" in diameter):

1. Place pole within clamp bracket and tighten screw using the black finger knob. Make sure that there is enough space above the clamp so that you have a few inches to slide the monitor in from above.
2. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp, and the monitor should snap securely into place.



Figure 7 - Pole Clamp

To remove the monitor, press tab on top of clamp shoe before sliding monitor up.

The pole clamp may be locked onto the monitor so that the two do not get separated. To do this:

1. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp and the monitor should snap securely into place.
2. Make sure that set screw hole on pole clamp aligns with corresponding hole on clamp shoe.
3. Remove black knob screw from pole clamp.

4. Using the Allen wrench supplied, secure pole clamp to monitor with the set screw provided.
5. Replace black knob screw.
6. To attach to pole, place pole within clamp bracket and tighten screw using the black finger knob.

4.2 Instrument Connections

Detailed connection instructions are provided in the BIS VIEW Operating Manual.

4.2.1 Connecting the BISx

1. **Connect the BISx to the monitor**

Holding the cylindrical connector with the flat side up, plug the BISx Monitor Interface Cable into the BISx port on the front of the monitor.

Once connected, the BISx need not be disconnected again. However, if you wish to disconnect the BISx cable from the monitor, carefully grasp the connector and pull. **DO NOT** pull or twist the cable.

2. **Connect the PIC to the BISx**

Turn the 10-pin connector of the PIC so that the BIS logo is facing up, then plug it into the BISx.

Note:

Once connected, the PIC need not be disconnected again, however, if you wish to disconnect the PIC, grasp the connector housing and pull firmly. **DO NOT** twist or pull apart by the cable wire.

4.2.2 Power Cord Connections

The BIS VIEW Monitoring System is designed to use only 3-conductor IEC hospital-grade power cords. Cords must be type SJE, SJT, or SJO. Align power cord connector to power cord port and insert firmly. Check for a firm connection.

4.3 Installation and Verification Procedure

1. Open packages and inspect for all components:
 - Monitor
 - Power cord
 - Pole clamp
 - BISx
 - PIC (Patient interface cable, connects BISx to patient)
2. Connect power cable to monitor, plug power plug into appropriate wall outlet.
 - Verify that light to right of ON/Standby button is yellow.
3. Start up monitor by pressing the ON/Standby button (lower right corner).

- Verify that light to right of ON/Standby button is green.
 - Verify all self-tests complete successfully. A beep tone sounds.
 - Verify next screen says “Connect BISx.”
4. Connect BISx to monitor. Connect PIC and sensor to BISx.
 - Verify screen says, “BISx Initialization Complete.”
 - Verify SENSOR CHECK begins.
 5. Disconnect power cord from rear of monitor.
 - Verify ‘OPERATING ON BATTERY BACKUP’ is displayed.
 - Verify battery icon displays below BIS number.
 6. Reconnect power cord.
 - Verify battery icon is not displayed below BIS number.
 - Verify “OPERATING ON BATTERY BACKUP” is not displayed.
 7. End of install.

5 CARE AND CLEANING

INTRODUCTION

This section describes:

- Care and cleaning procedures
- Preventive maintenance

5.1 Care and Cleaning

WARNING!

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

5.1.1 Cleaning the Monitor and BISx

Clean any spillage of blood or solutions on either the monitor or BISx as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely. Residual moisture inside the connector may affect BISx performance.

5.1.2 Disinfecting the Monitor and BISx

Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g. Lysol® Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes).

After cleaning, dry all areas except the monitor display screen (see below) with a lint-free absorbent paper towel. Wipe the BISx and PIC connector ends with alcohol and allow to dry completely.

WARNING!

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST GROUND LEAKAGE CURRENT BEFORE FURTHER USE.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA) AS HAZARDOUS GASES MAY RESULT.

Caution:

Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

5.1.3 Cleaning the Monitor Display

Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

6 PREVENTIVE MAINTENANCE

INTRODUCTION

The BIS VIEW system is designed so that no periodic adjustment or calibration is required. Suggested routine maintenance covered in this section includes:

- Periodic physical integrity inspection
- Replacing the PIC
- System checkout
- Checking the battery
- Checking leakage current

Instructions on replacing cables, connectors, the battery, the power supply and the clamp shoe are included in Section 8, “Servicing the BIS VIEW System” if replacement is necessary.

6.1 Physical Integrity Inspection

Periodically check the system (BIS VIEW monitor, BISx, PIC) for physical damage to cases and associated cables and connectors.

1. Inspect the cases of the monitor and the BISx to ensure that plastic is not cracked or broken.
2. Inspect the gasket seal around the case joining surfaces to insure the integrity of the splash resistance seal.
3. Inspect the cables and strain relief mechanisms.
4. Inspect the connectors for damage, faulty strain relief or contamination.

6.2 Replacing the PIC (Patient Interface Cable)

The Patient Interface Cable (also known as the PIC cable) is considered a consumable part of the system and is expected to wear out due to normal usage. The internal wires and/or connector contacts may fail with fatigue over time or become contaminated with foreign material. This is an expected occurrence, as it is with any equipment that utilizes lead wires or patient connection cables. Therefore, it is recommended that the PIC cable be tested on a periodic basis (see section 6.3 “System Checkout”) and replaced if it has been in service for more than two years.

The PIC cable date of manufacture is printed on each cable and is located on a white label wrapped around the PIC cable. The manufacturing date code is identified in one of the following methods:

- “PIC+ mmddyy” (month, day, year)
- “PIC+ mm/dd/yy” (month, day, year)
- “nnnnnnwwyy” (where ww is week and yy is year)

Replacing the PIC cable is an important routine maintenance action which will improve the reliability of the BIS monitoring system.

6.3 System Checkout

A system checkout should be done periodically to verify that all system components are in working order. To test the system from the BISx to the BIS sensor, you will need a Sensor Simulator (P/N 186-0137) or a Test Sensor (See Appendix I for more information). Follow the instructions below for System Checkout.

6.3.1 Monitor Checkout Procedure

The successful completion of this test will verify that the monitor is functioning and that all operator input (soft keys) and output (display and audio alarm) are OK.

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3, “BIS VIEW System Messages And Corrective Actions”.

1. Disconnect the BISx from the monitor.
2. Connect power cord to monitor. Plug power plug into appropriate wall outlet.
 - Verify that the light to the right of the ON/Standby button is yellow.
3. Start up monitor by pressing the ON/Standby button (lower right corner).
 - Verify that the light to the right of the ON/Standby button is green.
 - Verify all self-tests complete successfully. A beep tone sounds.
 - Verify next screen says “Connect BISx.”
4. Connect BISx to monitor with PIC and sensor.
 - Verify screen says, “BISx Initialization Complete.”
 - Verify SENSOR CHECK begins. (Note that if a BIS Extend Sensor is attached, you must press **[CONTINUE]** to proceed to the Sensor Check.)
5. Disconnect power cord from monitor.
 - Verify ‘OPERATING ON BATTERY BACKUP’ is displayed.
 - Verify battery icon displays below BIS number.

NOTE:

Since the BIS VIEW monitor has a built in battery backup, the monitor will power up with or without AC power applied. This step assures that this part of the test is performed under battery power

6. Reconnect power cord.
 - Verify battery icon is not displayed below BIS number.
 - Verify ‘OPERATING ON BATTERY BACKUP’ is not displayed.

NOTE:

Since the BIS VIEW monitor has a built-in battery backup, the monitor will power up with no AC power applied. This step assures that this part of the test is performed in AC operation.

IF ANY FAILURES ARE NOTED:

- Verify AC power outlet (wall outlet) is supplying AC Volts of 110vac to 240vac at a frequency of 50hz to 60hz. Move power cord to known good outlet.
- Verify AC power cord is good. Swap power cord with known good one.
- If monitor runs on battery when it is plugged in to AC power, the power supply may need replacement.
- If failure continues after above actions, the monitor will need to be serviced, see section 8.12, “What To Do With a Component That Requires Service.”

7. End of monitor checkout.

6.3.2 BISx Checkout Procedure

Periodically the BISx and associated cables and connectors should be inspected for physical damage and verification that the BISx will pass the DSC Self Test. Begin this procedure with the system components disconnected. The successful completion of this test verifies that the BISx circuits are functioning properly and that it is recognized by and communicates with the monitor.

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3,
“BIS VIEW System Messages And Corrective Actions”.

1. Using a known good BIS VIEW monitor (see Section 6.3.1 “Monitor Checkout Procedure”), start up the monitor with the BISx disconnected.
 - Verify that the screen message “Connect BISx” displays.
2. Connect the BISx that you are testing.
 - Verify that the screen message “Connect sensor or cable” displays.
3. Press the **[MENU]** soft key to access menu options.
4. Select **[Diagnostics]**.
5. Select **[Advanced Diagnostics]**.
6. Select **[DSC Self Test]** to initiate the test.
 - Verify that the display shows “DSC Self Test Results: PASS.” This takes approximately 20 seconds. Note that test results are posted in 4 tests for 2 channels. If a test fails, the failed test displays either “***” or the word, “FAIL.”
7. Select **[BACK]** and repeat the DSC Self Test while flexing cables to see if intermittent opens or shorts exist.

IF ANY FAILURES ARE NOTED:

- Swap BISx with known good one to verify that problem does not exist with the monitor.
- If failure is isolated to this BISx, it will need to be serviced. See section 8.12 “What To Do With a Component That Requires Service.”

8. Press **[HOME]** to exit. If PIC and Sensor are available, perform PIC Checkout Procedure. See section 6.3.3 “Patient Interface Cable (PIC) Checkout Procedure.”

6.3.3 Patient Interface Cable (PIC) Checkout Procedure

The successful completion of this test will verify function of the BIS VIEW system from the BISx circuits to the patient connector. Since the conductors used are located both in the BISx and the PIC, use a swapping technique to isolate the faulty component.

Use a Sensor Simulator (P/N 186-0137) or make a Test Sensor for this test. (See Section 10.3 “Test Sensor” for details.)

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3,
“BIS VIEW System Messages And Corrective Actions”.

1. Using a known good BIS VIEW monitor (see section 6.3.1 “Monitor Checkout Procedure) and a known good BISx (see section 6.3.2 “BISx Checkout Procedure) connect the PIC that you are testing to the BISx, and connect the BISx to the BIS VIEW monitor.
2. Press the monitor’s ON/Standby button to start up the monitor and BISx. At the completion of the power up self-test, verify that the screen message “Connect sensor or cable” displays.
3. Connect a Sensor Simulator (see Section 10.2) or Test Sensor (see Section 10.3) to the PIC cable.
4. A sensor check is initiated when the sensor and PIC are connected to the BISx. (It may also be initiated by pressing the **[SENSOR CHECK]** soft key. Note that if a BIS Extend Sensor is in use, you must press **[CONTINUE]** to initiate the check.) The message, “Sensor Check in Progress” appears. When the sensor successfully passes the test, the BIS Trend screen displays.
5. **If the Sensor Check is not immediately successful**, the Sensor Check Graphic Screen displays automatically. This screen shows a sensor with each electrode numbered. Colors indicate the status of each electrode.
 - White hollow circle – No status is available (Lead is off).
 - Green circle – The electrode impedance is within the acceptable range.
 - Red blinking circle – The electrode impedance is not within the acceptable range.

The impedance value for each electrode, in kilo ohms, appears on the screen along with its status:

- PASS - An electrode passes if the impedance for that electrode is less than 7.5 kilo ohms. The ground electrode (element #2) must be less than 30 kilo ohms to pass.
 - HIGH - An electrode is labeled “HIGH” if its impedance value is above 7.5 kilo ohms. As long as the combined impedance of electrodes #1 and #3 and the combined impedance of electrodes #1 and #4 are less than 15 kilo ohms, the sensor check will be considered successful.
 - NOISE - If the signal from the electrode goes beyond the measurable range, the label “NOISE” displays.
 - LEAD OFF - If the impedance check indicates that the electrode is not in contact with the patient, the label “LEAD OFF” displays.
6. **If the Sensor Check is successful, repeat the test** by pressing the **[SENSOR CHECK]** soft key. The Sensor Check Graphic Screen displays. During the test sequence, flex the cable and connections at the PIC/SENSOR, and PIC/BISx connections. Note that gentle flexing of these cables and connectors should not cause the Sensor Check to fail.

NOTE:

Sensor Check is used in clinical application as an indicator of the patient’s skin conductivity. When used with a Sensor Simulator or Test Sensor, the Sensor Check serves to test the cable conductors of the BISx and PIC, and the status indications noted above indicate the ability of the BISx and PIC to conduct the sensor check signal. Values that are too high indicate a need to investigate and possibly replace the PIC or BISx.

Expected Impedance Values

Sensor Simulator Values			Test Sensor Values		
Electrode #	Typical	Range	Electrode #	Typical	Range
1	5 K Ohms	4-6 K Ohms	1	1 K Ohms	1-2 K Ohms
2	10 K Ohms	8-17 K Ohms	2	1 K Ohms	1-3 K Ohms
4	4 K Ohms	3-5 K Ohms	4	1 K Ohms	1-2 K Ohms
3	3 K Ohms	2-4 K Ohms	3	1 K Ohms	1-2 K Ohms

6.4 Checking the Battery

The battery must be tested periodically to verify that the BIS VIEW Monitoring System will continue to operate during power outages. To test:

1. Charge the BIS VIEW monitor by leaving it plugged into A/C power for at least 6 hours. The monitor charges while in either Standby mode (yellow light) or ON (green light).
2. Power ON the BIS VIEW monitor (green light).
3. Disconnect the A/C cord from the wall supply.
4. Verify that the BIS VIEW Monitoring System operates reliably for 45 minutes.
5. Recharge the battery.

WARNING

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

LEAKAGE CURRENT MUST BE CHECKED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN WHENEVER INSTRUMENT CASE IS OPENED.

Caution:

Check the battery periodically by operating a BIS VIEW monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage, charge the battery for 6 hours to assure full capacity. If the BIS VIEW monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VIEW monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery, P/N 186-0208.

If the battery requires replacement, see Section 8.4, “Replacing the Battery”.

6.5 Checking Leakage Current

Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment. Each BIS VIEW system is carefully checked at the factory to verify that leakage current meets the UL60601-1 and IEC60601-1 safety standards.

The BIS VIEW monitor should be checked routinely for leakage current at least once a year. Always have the leakage current checked after a saline or blood spill, or immediately after a major surge in the house electrical system and after every time the monitor case has been opened. Keep in mind that liquids such as saline and Ringer's as well as blood are all excellent conductors of electricity. Avoid touching any part of the system with wet hands. Always work with clean, dry hands.

WARNING!

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS.

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST BEFORE FURTHER USE.

Leakage Current testing should be performed by a qualified Biomedical Engineering Technician or authorized personnel only.

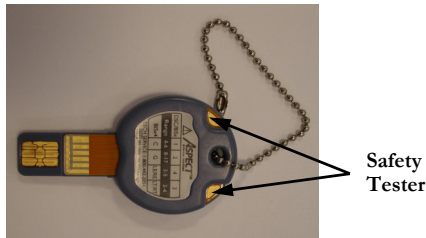
The BIS VIEW Monitoring unit **does not** contain a *Protective Earth Stud (GND Stud)*. Since the exposed metal parts on the rear of the BIS VIEW Monitor (Communication serial port and USB ports) are separated from live parts by double insulation, a ground continuity test does not apply to these parts. The components of the BIS VIEW Monitor that are connected to protective earth are contained within its enclosure and are not accessible to the user of the equipment. However, as stated in the operating manual, an enclosure leakage current test should be performed on the exposed metal parts and should be checked periodically to ensure that the integrity of the equipment's insulation system is maintained. The leakage current test should include measurement of ground wire leakage, enclosure leakage, and patient leakage.

Ground wire leakage typically can be performed automatically by connecting the A/C power cord of the BIS VIEW Monitor into a safety tester. The enclosure leakage may be measured by any safety test equipment that is capable of connecting to isolated conductive parts and measuring the current from those parts to earth. The patient connection terminals of many safety testers can be used for this purpose. The patient leakage current of the BISx can be

measured by connecting the patient connection terminals of a safety tester to a Sensor Simulator that is connected to the PIC.

To check BISx patient isolation:

1. Connect the Sensor Simulator to the PIC in place of a sensor. (See Appendix.)
2. Use a jumper to short the two terminals at the end of the simulator .
3. Connect the test lead to the shorted terminals. Make sure that you are not touching the simulator beyond this point.
4. Proceed to test instrument for leakage current as per established facility protocols and procedures for safety testing of medical devices.



7 DIAGNOSTICS AND TROUBLESHOOTING

INTRODUCTION

This section explains:

- General troubleshooting using built in diagnostic tools
- BIS VIEW Monitoring System troubleshooting procedure.
- Status messages, possible causes, and corrective actions

7.1 General Troubleshooting

The BIS VIEW Monitoring System has both automatic and manual diagnostic features. These features check the BIS VIEW Monitoring System's operability and status, and report software and hardware malfunctions.

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3 "BIS VIEW System Messages and Corrective Actions"

The **power-up** diagnostics run automatically the first time the unit is powered on, after the battery or power supply have been replaced, or after the Reset button has been pressed. Software image checksums and trend data memory are tested and repaired if necessary.

The **automatic** diagnostics run continuously in the background while the unit operates. These procedures check the BISx for the following conditions: interface faults, disconnect, lead off, and power faults.

The **manual** diagnostics are operator initiated using the monitor soft keys and menu choices. These procedures check the digital signal converter function within the BISx.

NOTE:

The manual diagnostics can be run safely while the patient is connected to the BIS VIEW Monitoring System; however, running the diagnostics will temporarily disrupt monitoring. Do not run the DSC Self Test during electro-cautery as it may erroneously indicate a failure of the BISx.

7.2 BIS VIEW Monitoring System Troubleshooting Procedure

The BIS VIEW Monitoring System consists of three major components: Monitor, BISx, and PIC/Sensor. By using the three-step Checkout Procedure and a component swapping technique, the component at fault can easily be determined.

Use the Checkout procedures in Section 6.3 “System Checkout” to test function of each component. The steps of this checkout procedure include:

- Monitor; test monitor and battery power functions
- BISx; recognition and DSC Self Test
- PIC and Sensor; recognition and Sensor Check test

Consult Section 7.3 “BIS VIEW System Messages and Corrective Actions” for messages that may occur and the appropriate action to take.

Consult Section 8 “Servicing the BIS VIEW System” for directions on replacing components and handling components that require service.

BISx Cable Problem Isolation

Note:

This BIS VIEW Monitoring System Service Information Manual contains the maintenance and diagnostic troubleshooting information necessary for qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal electronic components of the BISx or the BIS VIEW monitor.

The qualified user may replace the BISx cables by following the procedures in Section 8 “Servicing the BIS VIEW System.” If the cables or connectors are physically damaged, they will need to be replaced. If cables are suspect, the following may be of aid in determining which cable is defective.

The **Monitor Interface Cable** (monitor connector to BISx) is an 11-conductor cable that handles all communications to/from the BISx. It uses two twisted pair and a ground for digital data transmission and for the clock transitions that are used to generate power in the BISx housing. Therefore, failure in this cable is usually seen as failure to recognize the BISx (“Connect BISx” message).

The **Patient Interface Cable (PIC)** is a 10-lead conductor that brings in the patient’s EEG signal and also provides information about the sensor connected. If this cable fails, the system may indicate that the sensor is not connected or is illegal, or the Sensor Check may fail or restart on its own.

Problem Isolation Procedure: Use the following sequence to determine the most probable cable:

1. With no sensor connected, run DSC Self Test (see Section 7.2.2 “BISx Checkout Procedure):
 - If test fails or will not start, or the BISx is not recognized, the Monitor cable is likely suspect. This failure may also be related to a PCB problem in the BISx in which case the BISx must be replaced.
 - If test indicates PASS, continue to step 2.
2. Connect Sensor Simulator or Test Simulator. Run Sensor Check (see Section 7.2.3 “PIC Checkout Procedure)
 - If failure is noted, swap PIC with known good PIC cable and run again.
 - If failure repeats, the BISx or the BISx Bulkhead Connector is suspect. This failure may also be related to a PCB problem in the BISx in which case the BISx must be returned to Aspect for service.

7.3 BIS VIEW System Messages and Corrective Actions

When an alarm is triggered, a message appears in the Message Region of the screen. Possible messages and the recommended operator actions are listed below:

BIS VIEW Messages and Operator Actions

Status Messages:	Possible Causes:	Corrective Actions:
None (screen is blank)	Monitor has not completed its power ON diagnostics tests.	<ol style="list-style-type: none"> 1. Monitor may take up to three minutes to initialize trend memory. Do not disconnect equipment or press keys during this time. 2. If several minutes have passed, restart monitor. 3. Reset monitor. 4. Replace monitor.
Connect BISx	<ol style="list-style-type: none"> 1. BISx disconnected. 2. Defective BISx cable. 3. Defective BISx. 4. Defective monitor. 	<ol style="list-style-type: none"> 1. Connect BISx. Verify all cable connections. 2. Replace Monitor Interface Cable. 3. Replace the BISx. 4. Replace monitor.
Re-prep Sensor [0013]	<ol style="list-style-type: none"> 1. Sensor is not fully in contact with patient's skin. 2. Incorrect sensor application. 3. Poor sensor connections. 4. Sensor Check fails 5. Defective PIC. 6. Defective BISx. 	<ol style="list-style-type: none"> 1. Press electrodes. 2. Read Instructions on sensor package to ensure correct sensor placement. 3. Check sensor connections. 4. Re-prep again or replace sensor. Verify Sensor Check passes. 5. Replace the PIC. 6. Replace BISx Bulkhead Connector or replace BISx.

Status Messages:	Possible Causes:	Corrective Actions:
Sensor Disconnected [0014]	<ol style="list-style-type: none"> 1. Disconnected sensor. 2. Poor or contaminated connection between sensor and PIC. 3. Disconnected PIC. 4. Defective PIC. 5. Defective BISx. 	<ol style="list-style-type: none"> 1. Connect the sensor. 2. Connect/clean connection between sensor and PIC. 3. Connect the PIC. 4. Replace the PIC. 5. Replace BISx Bulkhead Connector or replace BISx.
Last Sensor Check Failed [0016]	<ol style="list-style-type: none"> 1. At least one element of sensor has too high impedance, and EXIT pressed (before sensor check completes). 2. Poor sensor connection 3. Incorrect sensor application. 4. Defective PIC. 5. Defective BISx. 	<ol style="list-style-type: none"> 1. Verify Sensor Check passes. 2. Check sensor connection. 3. Read Instructions on sensor package and re-apply sensor. 4. Replace the PIC. 5. Replace BISx Bulkhead Connector or replace BISx.
Unrecoverable BISx Error [0024]	<ol style="list-style-type: none"> 1. Poor communication between BISx host cable and monitor. 2. Defective BISx. 3. Defective monitor. 	<ol style="list-style-type: none"> 1. Unplug BISx from monitor. Power down monitor. Power up monitor, then reconnect BISx. If error returns contact Technical Service. 2. Replace the BISx. 3. Replace the monitor.

Status Messages:	Possible Causes:	Corrective Actions:
Excessive Artifact Detected in Signal [0027]	<p>The Signal Quality is less than half of the level desirable for optimal monitoring conditions.</p> <ol style="list-style-type: none"> 1. Artifact, such as those generated by motion or eye blinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. <p>Note: This message may occur as a result of artifact (non-EEG signal) such as those generated from motion (patient movement or eye blinks) or the presence of electro-cautery, warming blankets, or other devices.</p>	<ol style="list-style-type: none"> 1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.

Status Messages:	Possible Causes:	Corrective Actions:
Data unavailable due to poor signal quality [0028]	<p>The signal quality is too low to accurately calculate a BIS value. The BIS value and other trend variables that are adversely affected by artifact are not displayed</p> <ol style="list-style-type: none"> 1. Artifact, such as those generated by motion or eye blinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. <p>Note: This message may occur as a result of artifact (non-EEG signal) such as those generated from motion (patient movement or eye blinks) or the presence of electro-cautery, warming blankets, or other devices.</p>	<ol style="list-style-type: none"> 1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
BIS Out of Target Range Low [0029] High [0030]	<p>The BIS has fallen outside the target range set by the user.</p>	<ol style="list-style-type: none"> 1. Check patient. 2. Take note of BIS at limit set by user.

Status Messages:	Possible Causes:	Corrective Actions:
Isoelectric EEG Detected [0031]	<p>No discernible EEG activity is detected for sixty-three seconds; SR=100.</p> <p>Note: This message notifies user of a flatline EEG. This is a normal condition when Sensor Simulator or Test Sensor is connected.</p>	<p>If unintended:</p> <ol style="list-style-type: none"> 1. Check patient vital signs, dosage, etc. 2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self Test passes. 5. Verify PIC. Use Test Sensor or Sensor Simulator and Sensor Check.
Operating On Battery Backup [0033]	The AC power has been lost and the monitor is running on the battery. The battery keeps the monitor operating for approximately 45 minutes (when the battery is fully charged).	<ol style="list-style-type: none"> 1. Restore the AC power. 2. Verify power cord. 3. Replace power supply.
Battery Voltage Low [0034]	There are only a few minutes of battery life left.	Restore AC power to avoid automatic shutdown.
Sensor Negative Ground Fault [0092] Sensor Positive Ground Fault [0093]	Problem is detected relating to sensor ground element.	<ol style="list-style-type: none"> 1. Disconnect and examine sensor connection. Clean any contamination present. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
Sensor Overcurrent [0094]	Sensor is using too much current.	<ol style="list-style-type: none"> 1. Disconnect and examine sensor connection. Clean any contamination. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.
No more Uses for this Sensor [0095]	Sensor has been connected and disconnected too many times.	Replace the sensor.

Status Messages:	Possible Causes:	Corrective Actions:
Sensor Invalid [0096]	<ol style="list-style-type: none"> 1. Poor or contaminated connection between sensor and PIC. 2. An incorrect or defective sensor has been connected to the PIC. 3. Defective PIC. 4. Defective BISx. 	<ol style="list-style-type: none"> 1. Connect/clean connection between sensor and PIC. 2. Replace the sensor. 3. Replace the PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
Sensor used for over 24 hours [109]	Sensor was attached to system for more than 24 hours.	Replace sensor.
Unrecoverable Monitor Error [471]	Monitor was unplugged during upgrade, or battery ran out unexpectedly and software did not have time to detect it (check error log for low battery entries)	<ol style="list-style-type: none"> 1. Unplug BISx and power cord and turn monitor off. 2. Reconnect AC power and restart monitor. 3. Press the reset button. 4. If error persists, replace monitor.
Data export error [512]	(See Message 3000)	
Date and time not changed [513]	A case was in progress when the time/date was changed.	Change the date/time after the case has finished.
Trend memory error [516]	Trend memory is full or data has been corrupted.	Disconnect the BISx and restart monitor. Do not reconnect the BISx until directed.
Unrecoverable BISx error [517]	(See Message 1000)	
No data available [524]	<ol style="list-style-type: none"> 1. No data has been written to the BISx/monitor. 2. Defective BISx. 3. Defective monitor. 	<ol style="list-style-type: none"> 1. Try again after a case has been run. 2. Replace BISx. 3. Replace monitor.

Status Messages:	Possible Causes:	Corrective Actions:
System error [533, 538]	(See Message 2000)	
Export halted: USB drive not detected [539]	<ol style="list-style-type: none"> 1. Removable drive is not connected properly to USB(A) port. 2. Drive is not formatted properly. 3. Drive is incompatible or defective. 4. USB port is defective. 	<ol style="list-style-type: none"> 1. Check connection. 2. Format drive to FAT32. 3. Replace drive. 4. Replace monitor.
Export halted: USB drive full [540]	<ol style="list-style-type: none"> 1. Removable drive is not connected properly to USB(A) port. 2. Drive “write protect” is locked. 3. Drive is incompatible or defective. 4. Drive is full. 	<ol style="list-style-type: none"> 1. Check connection. 2. Verify “write protect” switch on the drive is set to “unlock” position. 3. Replace drive. Contact your Aspect Technical Service representative for a list of compatible drives. 4. Replace drive.
Export halted: BISx not detected [541]	<ol style="list-style-type: none"> 1. BISx disconnected. 2. Defective BISx cable. 3. Defective BISx. 4. Defective monitor. 	<ol style="list-style-type: none"> 1. Connect BISx. Verify all cable connections. 2. Inspect/repair cable at connector end. 3. Replace the BISx. 4. Replace monitor.
Export halted: USB drive full [544]	(See Message 540)	
Export halted: USB drive not detected [545]	(See Message 539)	

Status Messages:	Possible Causes:	Corrective Actions:
Unrecoverable BISx Error [1000-1999]	<ol style="list-style-type: none"> 1. Poor connection between BISx monitor cable and monitor. 2. Defective BISx. 3. Defective monitor. 	<ol style="list-style-type: none"> 1. Unplug BISx from monitor and plug in again. If necessary, unplug power cord and plug in again to shut down monitor completely. Then plug in and +re-start monitor. 2. Replace the BISx. 3. Replace the monitor.
Unrecoverable Monitor Error [2000-2999] Hardware Timer Error [2902]	<p>A system error has occurred. The monitor may stop operating. This can occur if the BISx is unplugged while the monitor is starting up.</p> <p>A system timer error has occurred.</p>	<ol style="list-style-type: none"> 1. Follow on-screen instructions (if any). 2. Turn the monitor off, then on again. 3. Reset monitor. 4. Replace monitor.
Data Export Error [3000-3999]	<p>The data export was not successful.</p> <ol style="list-style-type: none"> 1. Removable drive is not connected properly to USB(A) port. 2. Drive "write protect" is locked. 3. Drive is not formatted properly. 4. Drive is incompatible or defective. 5. Drive is full. 	<ol style="list-style-type: none"> 5. Make sure the removable drive is connected properly to the USB(A) port. 6. Verify that "write protect" switch on the drive is set to "unlock" position. 7. Verify that the drive is formatted as FAT32. 8. Replace drive. Contact your Aspect Technical Service representative for a list of compatible drives. 9. Replace drive.
Unable to update software [4000-4999]	<ol style="list-style-type: none"> 1. Software has already been updated to the current revision. 2. A software error has occurred. 	<ol style="list-style-type: none"> 1. Check revision. 2. Restart monitor. 3. Reset monitor. 4. Verify that drive is formatted as FAT32. 5. Replace drive.
Trend Memory Error [5000-5999]	<p>A memory error has occurred.</p>	<ol style="list-style-type: none"> 1. Restart monitor. 2. Reset monitor. 3. Replace monitor.

8 SERVICING THE BIS VIEW SYSTEM

INTRODUCTION

This section provides instructions for replacing the PIC, BISx, and the monitor, and for removing and replacing parts of the monitor and the BISx. If a component needs to be serviced, please consult Sections 8.11 and 8.13 for instructions on packaging and shipping.

The BIS VIEW Monitoring System is designed to be easily serviced by using the built in diagnostic routines (see Section 7 “Diagnostics and Troubleshooting”) and the major component swapping techniques described below. Replacement part numbers are listed in Section 10.1, “Accessories and Spare Parts List.”

8.1 Replacing the PIC

Parts Required:

Patient Interface Cable (PIC Plus) P/N 186-0107

Tools Required:

None

To replace the PIC, unplug the PIC cable from the BISx Bulkhead Connector by grasping the connectors (NOT the cable!) and firmly pulling the two sections apart. DO NOT twist or pull apart by the cable wire.

To attach the replacement PIC cable to the BISx, align and press the PIC and BISx connectors together firmly.

8.2 Replacing the BISx

Parts Required:

BISx with Patient Interface Cable; P/N 185-0145-AMS

Tools Required:

None

To replace the BISx:

Disconnect the BISx from the front of the monitor. To do this, carefully grasp the connector on the BISx Monitor Interface Cable and pull. DO NOT twist or pull on the cable.

If necessary, unplug the PIC cable from the BISx by grasping the connector (NOT the wires!) and firmly pulling it out of the BISx Bulkhead Connector. DO NOT twist or pull apart by the cable wire.

To install the replacement BISx, hold the cylindrical connector with the flat side up (at 12 o'clock position) and insert firmly into BISx port on front of monitor.

To re-attach the PIC cable, align the PIC and BISx connectors and press together firmly.

8.3 Replacing the Monitor

Parts Required:

BIS VIEW Monitor P/N 185-0205

Tools Required:

None

To replace the monitor:

1. Put monitor in Standby mode by pressing the ON/Standby button. The light to the right of the button should be yellow or off.
2. Unplug the power cable from the wall and remove it from its receptacle in the rear of the monitor.
3. Disconnect the BISx from the front of the monitor. To do this, grasp the connector on the BISx Monitor Interface Cable and pull. DO NOT twist or pull on the cable.
4. If necessary, dismount monitor from pole clamp by removing set screw from clamp, then depressing top of clamp shoe (blue plastic clip at top of aluminum pole clamp) and slide the monitor up and off of the clamp.
5. To install the replacement monitor, insert power cord into receptacle on rear of monitor.
6. To install the BISx, hold the cylindrical connector with flat side up (at 12 o'clock position) and insert firmly into BISx port on front of monitor.
7. Re-mount pole clamp assembly.

8.4 Replacing the Battery

Parts Required:

Battery Replacement Kit P/N 186-0208

Tools Required:

Philips #2 screwdriver

Caution:

All repairs to the BIS VIEW Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

To replace the battery, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the monitor.
2. Lay monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.



3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. Note the position of the battery cable.
4. Squeeze the battery connector latch to disengage it from the back of the monitor and remove the old battery.



5. Lay the new battery in the recess with the wires at the top, and plug in the connector.
6. Replace the cover and four screws (hand-tighten only) and reconnect the A/C power cord.

8.5 Replacing the Power Supply

Parts Required:

Power Supply Replacement Kit P/N 186-0216

Tools Required:

Philips #2 screwdriver

Caution:

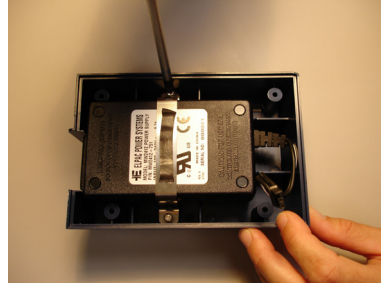
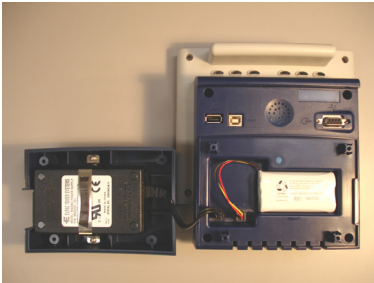
All repairs to the BIS VIEW Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

WARNING:

POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VIEW POWER SUPPLY.

To replace the power supply, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the BIS VIEW monitor.
2. Lay the monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. The power supply is located inside the cover.
4. Unplug (squeeze and pull to remove) the battery and the power supply connectors.



5. Remove screws from the power supply bracket and remove the old power supply.
6. Insert new power supply into the cover, lining up the A/C power receptacle with the cutout in the cover.
7. Replace power supply bracket and install screws (hand-tighten only).
8. Reconnect the power supply.
9. Reconnect the battery.
10. Replace the cover and 4 screws (hand-tighten only) and reconnect the A/C power cord.

8.6 Replacing the Clamp Shoe

Parts Required:

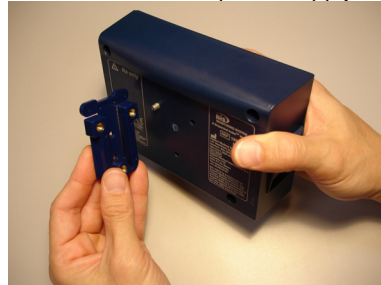
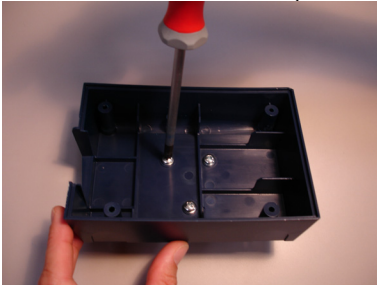
Shoe Clamp Replacement Kit P/N 186-0217

Tools Required:

Philips #2 and #8 screwdrivers

To replace the Clamp Shoe, you will need Philips #2 and #8 screwdrivers. The power supply must be removed to access the Clamp Shoe screws. Follow the instructions below:

1. Unplug A/C line cord from the BIS VIEW monitor.
2. Lay the monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. The power supply is located inside the cover.
4. Unplug (squeeze and pull to remove) the power supply connector.
5. Remove screws from the power supply bracket and remove the power supply.



6. Remove the three screws that attach the Clamp Shoe to the back panel.
7. Replace the Clamp Shoe and attach it to the back panel with the three new screws provided in the kit (hand-tighten only).
8. Insert power supply into the cover, lining up the A/C power receptacle with the cutout in the cover.
9. Replace the power supply bracket and install screws (hand-tighten only).
10. Reconnect the power supply.
11. Replace the cover and 4 screws (hand-tighten only) and reconnect the A/C power cord.

8.7 Replacing the BISx Monitor Interface Cable

Caution:

All repairs to the BIS VIEW Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

Use only the parts and tools specified. Use of any others may damage the instrument.

8.7.1 Parts and Tools Required

Parts Required:

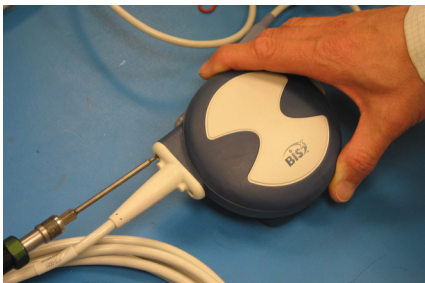
BISx Monitor Cable Replacement Kit;
P/N 186-0201-AMS includes:
BISx Monitor Interface Cable P/N
175-0061-GA
Gasket, P/N 150-0187
Torx head screws, P/N 606-0008

Tools Required:

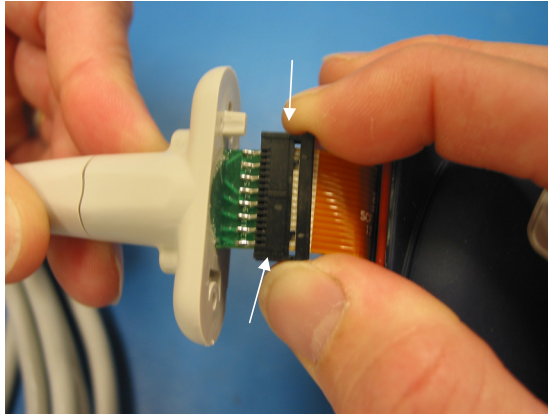
Torque screwdriver with Torx bit size T-7.



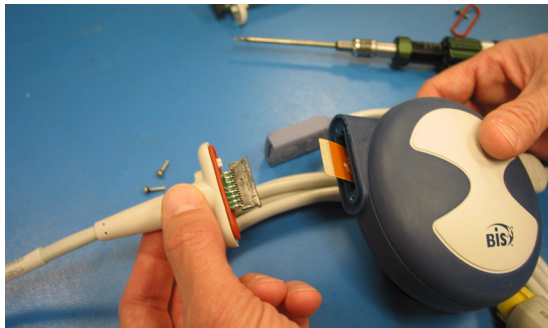
8.7.2 Procedure:



1. Disconnect BISx from the monitor.
2. Remove screws from the bulkhead of the old Monitor Interface Cable. Discard screws.



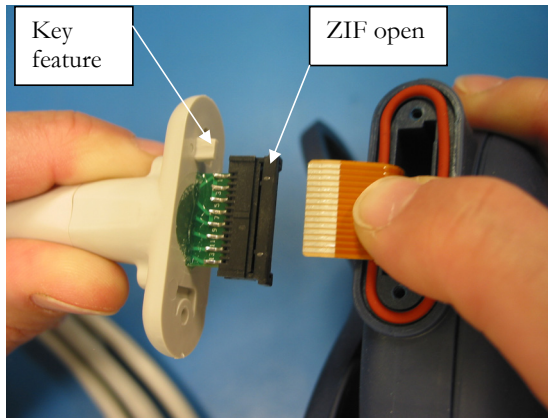
3. Open the ZIF connector by pulling away from the bulkhead.



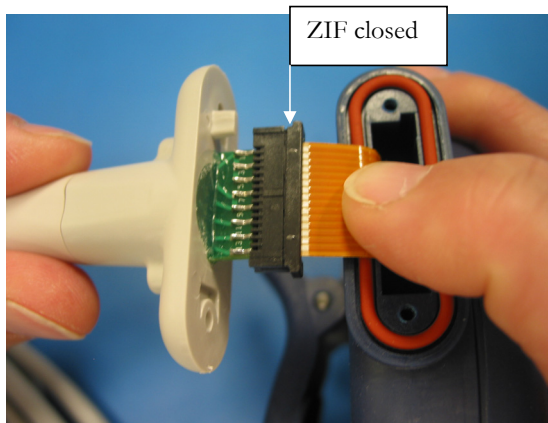
4. Disconnect from the flex cable. Discard the old gasket.



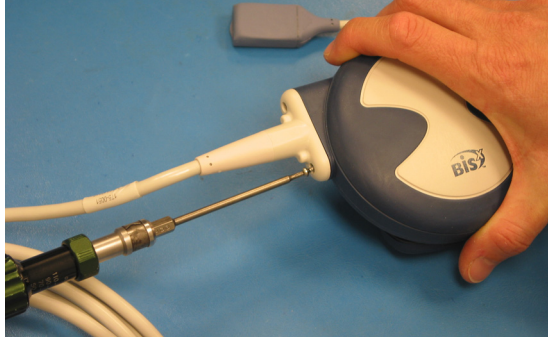
5. Set the new gasket in the groove of the BISx housing.



6. Align the key feature on the bulkhead and the BISx unit. Attach the flex cable from the BISx to the ZIF connector on the replacement cable.



7. Ensure that the flex cable is fully inserted into the ZIF and close the ZIF connector by pushing toward the bulkhead. Carefully feed the flex cable into the housing and seat the cable bulkhead to the BISx housing.



8. Using the screws provided, set the screws in the holes. Slowly tighten to 45 in-oz.

8.8 Replacing the BISx Bulkhead Connector

Caution:

All repairs to the BIS VIEW Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

Use only the parts and tools specified. Use of any others may damage the instrument.

8.8.1 Parts and Tools Required

Parts Required:

BISx Bulkhead Replacement Kit P/N 186-0202 includes:

BISx Bulkhead,
P/N 175-0052
Gasket, P/N 150-0187
Torx head screws, P/N 606-0008

Tools Required:

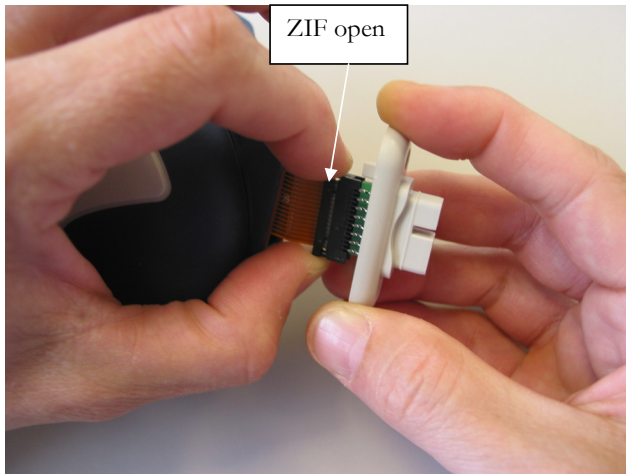
Torque screwdriver with Torx bit size T-7.



8.8.2 Procedure:



1. Disconnect BISx from the monitor and remove Patient Interface Cable from BISx.
2. Remove screws from the bulkhead. Discard screws.



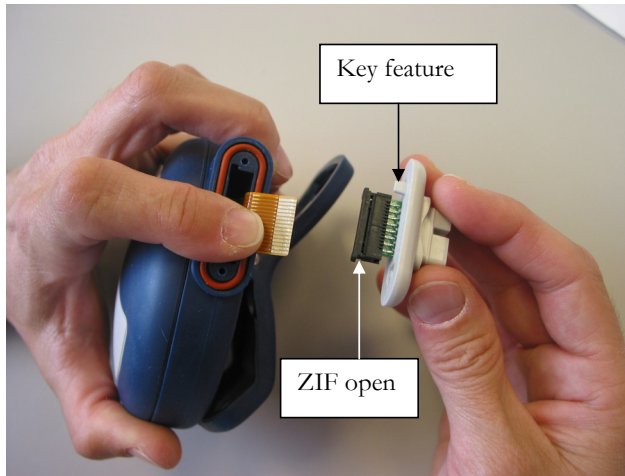
3. Open the ZIF connector by pulling away from the bulkhead.



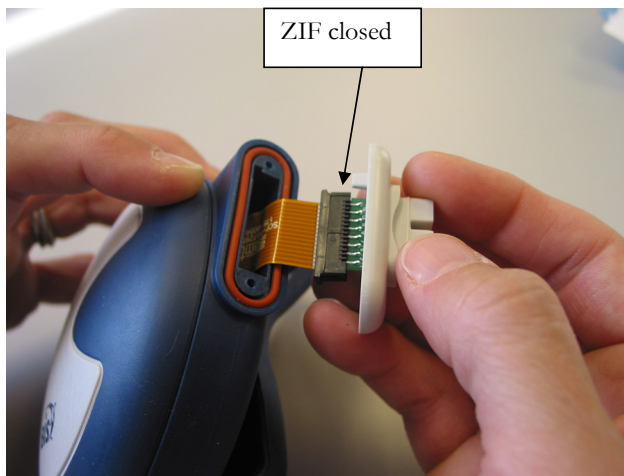
4. Disconnect from the flex cable. Discard the old gasket.



5. Set the new gasket in the groove of the BISx housing.



6. Align the key feature on the bulkhead and the BISx unit. Attach the flex cable from the BISx to the ZIF connector on the replacement bulkhead.



7. Ensure that the flex cable is fully inserted into the ZIF and close the ZIF connector by pushing toward the bulkhead. Carefully feed the flex cable into the housing and seat the bulkhead to the BISx housing.



8. Using the screws provided, set the screws in the holes. Slowly tighten to 45 in-oz.

8.9 Using the Reset Button

The Reset button is located on the back panel of the monitor. If necessary, the software can be reset by accessing this button with a ballpoint pen, paper clip or other similar tool.

8.10 BISx Checkout and Safety Tests

1. Perform DSC Self Test. See Section 6.3.2 “The BISx Checkout Procedure” or refer to the BIS VIEW Monitoring System Operating Manual.
2. Verify that all test sections PASS.
3. Install a known good PIC cable.
4. Connect a Sensor Simulator or Test Sensor tool as described in Section 10 “Appendix I.”
5. Perform a Patient Interface Cable (PIC) Checkout Procedure as described in Section 6.3.3. “PIC Checkout Procedure.” For more detail, refer to the BIS VIEW Monitoring System Operating Manual.
6. Perform a leakage (electrical safety test) according to the appropriate institution requirements.
7. If appropriate, perform a Hipot test according to institution requirements.
8. End of Procedure.

8.1.1 Performing a Software Update

The BIS VIEW system software may be updated by attaching a removable drive containing the update to the USB port on the rear of the monitor. The progress of the update displays on the monitor screen. When the update is complete, the user is asked to reset the system.

Notes:

The monitor must be connected to A/C power to perform the update.

When software is updated, all monitor configuration settings will be lost. Additionally, previously recorded data may be lost. Therefore, configuration settings and previous data should be recorded before the software update is performed.

Follow these steps to perform the update:

Caution:

Do not disconnect the BISx during the software update.

1. Before attempting an update, be sure to record your institution's saved settings, as they may be erased during the update procedure. See the BIS VIEW Operating Manual Section 3.6.3.5 "Settings: Active and Saved Monitor Settings" for instructions.
2. Power the monitor down completely by unplugging the power cord and then pressing the ON/Standby button until the light on the right side of the button goes out.
3. Re-connect the power cord to AC power, then press the ON/Standby button to start up the monitor. The light should be green.
4. Insert the USB drive containing the software update into the USB port (Type A) at the rear of the monitor.
5. Press **[MENU]** to access the Main Menu.
6. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**, then press **[SELECT]**. The Maintenance Menu displays.
7. Press **[Software Update]**. As soon as the updating device is detected, the message "Updates Detected" appears on the screen.
8. Press **[Continue]** to initiate the update. (To skip the update, Press **[Cancel]**. The monitor will operate with the current software.) The update begins. Do NOT remove the USB drive during the updating process.
9. If the message, "Connect BISx to monitor" appears on the screen, a BISx software update is available. Connect the BISx to continue with the update, or press **[Cancel]** to skip the update.
10. When the update is complete, the message "Update Complete" appears. Press **[RESET]**. The monitor and BISx will reset, and you can then resume normal operation.

8.12 What to do with a Component that Requires Service

Contact your local distributor to determine where servicing will occur. Aspect's Technical Service Department will assist you in isolating the problem to a specific component. Have the equipment available when you call so that you can supply the appropriate serial numbers and a detailed description of the problem. If it becomes necessary to return a unit directly to Aspect Medical Systems, follow the procedure below:

- Contact Aspect's Technical Service Department to obtain a Returned Materials Authorization (RMA) number. (The Technical Service phone number is printed on the back cover of this manual.) The RMA number must appear on the outside of the shipping container.
- Use the original shipping container, if available, or equivalent packaging to protect the product. Seal the package with reinforced packing tape rather than plastic or masking tape. Mark shipping or storage container FRAGILE.
- If the repair or replacement is covered by warranty or service agreement, Aspect will bear the costs of shipping the repaired or replacement product back to the user. All other shipping costs shall be paid by the user.

8.13 Repackaging for Shipping and Storage

If it becomes necessary to return the monitor to the factory, use the original shipping container to protect the product. Seal the package with reinforced packing tape rather than plastic or masking tape. Mark shipping container FRAGILE.

9 SPECIFICATIONS AND WARRANTY

INTRODUCTION

This section includes:

- General specifications of the BIS VIEW monitor and accessories
- Electromagnetic compatibility specifications
- Warranty

9.1 General Specifications

This section lists specifications for the BIS VIEW Monitoring System.

General Specifications:

Product Description:	BIS (Bispectral Index) monitoring system for display of processed data and real-time EEG waveforms
Monitor Weight:	2.65 lbs (1.2 kg)
Monitor Dimensions:	6 in wide x 6.5 in high x 5 in deep (15.2 cm x 16.5 cm x 12.7 cm)
Display Size:	3.6 in (9.1 cm)
Digital Output:	USB ports A, B, RS232 serial port
Power Requirements:	100-240 VAC, 50-60 Hz, 0.7 ampere max.
Electrical Safety:	Conforms to: UL 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1
Battery Backup:	45 minutes at full operation Recharge Time: 6 hours
Software Updates:	User-via USB port (Type A)

EEG Specifications:

Epoch Duration:	2 seconds
Artifact Rejection:	Automatic
Input Amplifier Range	+/- 1 mV
EEG Scales:	One Channel Display: 25 μ V/div (+/- 50 μ V full scale)
EEG Sweep Speed:	25 mm/sec
Computed Parameters:	Bispectral Index, EMG, SR and Signal Quality Indicator
User-defined Displays:	Trend and real-time EEG waveforms
Update Rate:	1 second for BIS number, 10 seconds for Trend
Alarms:	Auditory and visual, user adjustable limits
Filters:	2 – 70 Hz with notch

BISx Specifications:

BISx:	
Weight:	10.0 oz (0.284 kg) including integral cable
Dimensions:	3.75 in diameter x 2.5 in thick (9.5 cm x 6.3 cm)
Cable Length:	9 ft (2.7 m) Integral BISx Cable 4 ½ ft (1.4 m) from BISx to sensor connector
Analog to Digital Converter:	Noise-shaped sigma-delta
Sampling Rate:	16,384 samples/second
Resolution:	16 Bits at 256 samples/second
Input Impedance:	50 Mohms typical
Noise:	< 0.3 μ V RMS (2.0 μ V peak-to-peak); 0.25 Hz to 50 Hz
Common Mode Rejection: (Isolation mode)	110 dB at 50/60 Hz to earth ground
Frequency/Bandwidth:	0.16 – 450 Hz

Type of Protection against Electric Shock of the System:

Class 1: Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. The BIS VIEW monitor utilizes a commercial Class I medical-grade power supply which provides for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation. However because all components of the BIS VIEW that are classified as Protective Earth are contained within the power supply enclosure and are not accessible to the user, all exposed metal is classified as Functional Earth, not Protective Earth, and a ground continuity test is not recommended. Note that all exposed metal parts on the rear of the BIS VIEW monitor are separated from live parts by double insulation

Degree of Protection against Electric Shock of the System:

Type BF: Equipment providing a degree of protection against electric shock regarding allowable leakage currents and reliability of the protective earth ground connection with an F-type applied part. An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth. The circuitry inside the BIS VIEW monitor is isolated from the mains in accordance with IEC60601-1. Patient isolation is accomplished within the BISx.

Degree of Protection against effects of Cardiac Defibrillation:

The BIS VIEW system provides protection for the operator and patient during cardiac defibrillation. This protection is achieved via the isolation barrier within the BISx.

Degree of Protection against the Ingress of Water:

Monitor degree of protection rating: IPX2 (ingress of water vertically dripping).
BISx degree of protection rating: IPX4 (splash proof).

Mode of Operation of the System:

Continuous: Operation under normal load for a normal period without exceeding the specified limits of temperature.

Classification:

MEDICAL ELECTRONIC EQUIPMENT

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.® WITH RESPECT TO
ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN
ACCORDANCE WITH UL 60601-1, IEC 60601-1, IEC 60601-2-26,
CAN/CSA-C22.2#601.1.

9.2 Electromagnetic Compatibility Specifications

The BIS VIEW Monitoring System requires special precautions regarding Electromagnetic Compatibility (EMC). The BIS VIEW system must be installed and put into service according to the EMC guidance information provided in this section.

Portable and mobile radio frequency communications equipment can affect the operation of the BIS VIEW Monitoring System. Refer to the EMC guidance information and Cautions provided in this manual.

9.2.1 Accessories

The BIS VIEW Monitoring System complies with the requirements of IEC 60601-1-2:2001 when used with the accessories listed in Section 2 of the Operating Manual. In addition, the BIS VIEW system must be used only with the power cord provided.

When using the Software Upgrade Device to load new versions of software into the BIS VIEW monitor, no cables or other accessories should be connected to the device. The BIS VIEW monitor should be connected to the mains through the appropriate power cord, and the Software Upgrade Device should be plugged into the USB-A connector on the back of the device.

Caution:

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VIEW Monitoring System.

9.2.2 IEC 60601-1-2:2001 Electromagnetic Compatibility Guidance

This section provides the appropriate specification tables for the BIS VIEW Monitoring System as per IEC 60601-1-2.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The BIS VIEW Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VIEW system should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The BIS VIEW Monitoring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The BIS VIEW Monitoring System is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Caution:

The BIS VIEW system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VIEW monitor should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity


The BIS VIEW system is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VIEW system should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines.	±2 kV for power supply lines. ±1 kV for input/output lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical hospital environment. If the user of the BIS VIEW system requires continued operation during power mains interruptions longer than 45 minutes, it is recommended that the BIS VIEW monitor be powered by an uninterruptible power supply or an additional battery.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.

NOTE: UT is the AC mains voltage prior to the application of the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VIEW Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VIEW system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BIS VIEW system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$, 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$, 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by electromagnetic site survey ^a , should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BIS VIEW system is used exceeds the applicable RF compliance level above, the BIS VIEW system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BIS VIEW system^b Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BIS VIEW Monitor

The BIS VIEW Monitoring System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BIS VIEW system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIS VIEW system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency ranges applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

9.3 Warranty

Aspect warrants to the initial Purchaser that the BIS VIEW monitor and the BISx (“Warranted Product”) will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year (“Warranty Period”) from the date of its initial shipment to Purchaser. Excluded from this warranty are expendable components and supply items such as, but not limited to, electrodes, cables, and prep solutions. Aspect’s obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Aspect reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Aspect directly (see contact information on the back cover of this manual). Aspect will authorize Purchaser to return the Warranted Product (or part thereof) to Aspect. Aspect shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Aspect’s property. In the course of warranty service, Aspect may but shall not be required to make engineering improvements to the Warranted Product or part thereof. If Aspect reasonably determines that a repair or replacement is covered by the warranty, Aspect shall bear the costs of shipping the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by Purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If Purchaser ships a Product to Aspect in unsuitable packaging, any physical damage present in the Product on receipt by Aspect (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of Purchaser.

This warranty does not extend to any Warranted Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; that have been used in violation of Aspect’s instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than Aspect; or that have been disassembled, serviced, or reassembled by anyone other than Aspect, unless authorized by Aspect. Aspect shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Aspect makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Aspect or an Aspect-authorized distributor or (c) with respect to any product sold under a brand name other than Aspect Medical Systems, Inc.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR ASPECT'S PRODUCTS, EXTENDS ONLY TO THE PURCHASER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ASPECT'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY ASPECT IN CONNECTION THEREWITH. ASPECT SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT. EXCEPT AS SET FORTH HEREIN, ALL PRODUCTS ARE SUPPLIED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

10 APPENDIX I

10.1 Accessories and Spare Parts List

MAJOR COMPONENTS AND SENSORS:	
185-0205	BIS VIEW Monitor
185-0145-AMS	BISx
186-0107	PIC+, for BISx
186-0106	BIS Quatro Sensor
186-0200	BIS Pediatric (XP) Sensor
536-0047	Power Cord 6' North America
ACCESSORIES:	
150-0037	Pole Clamp Assembly
150-0058	BIS Monitor Stand
186-0104	BIS Sensor Dispenser
186-0137	Sensor Simulator
PARTS:	
186-0208	Battery Replacement Kit
186-0216	Power Supply Replacement Kit
186-0217	Shoe Clamp Replacement Kit
186-0201-AMS	BISx Host Cable (Monitor Cable) Replacement Kit
186-0202	BISx Bulkhead Replacement Kit
186-1003	Battery/ Power Supply Cover Assembly with Shoe Clamp
150-0272	Handle, VIEW monitor
675-0022	Cable wrap (Blue, hook & loop)
MISCELLANEOUS:	
180-0061	Empty carton, with foam, BIS VIEW
536-0044	RS-232 Cable, approx 6 ft. length
186-0170	J-Hooks
635-0007	Foot, rubber .75"

Operating Manuals for BIS Monitoring Systems are available at:
www.aspectmedical.com/asrs

10.2 Sensor Simulator: P/N: 186-0137

Instructions for Use

Insert 2CH/4CH BIS Sensor Simulator service tool into patient interface cable. Impedance test will be initiated by BIS Monitoring System when it detects that simulator has been inserted.

Description of tool:

The 2CH/4CH BIS Sensor Simulator is a service tool that allows for the verification of proper impedance values being detected by the BIS Monitoring System during the “Sensor check”. This test is part of the initial test that each monitor performs. The simulator also allows for safety testing of BIS monitors in the field by allowing connection of the test equipment to the monitor via the patient interface cable (PIC).

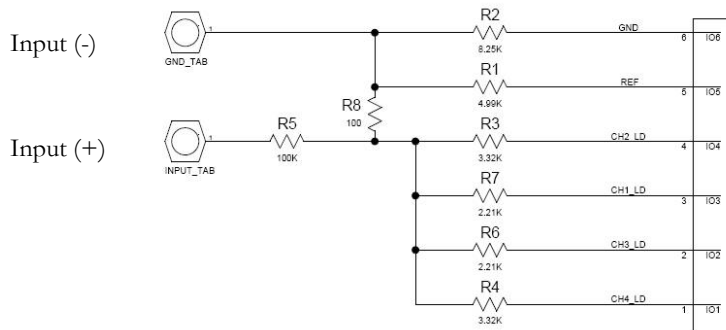


Figure 8 - Schematic of the BIS Sensor Simulator

Schematic of the 2CH/4CH BIS Sensor Simulator circuitry. IO3 – IO6 connect to 4 input signal pins on a 2 channel patient interface cable. (IO1 – IO6 connect to 6 input signal pins on a 4 channel patient interface cable.) The Inputs (+ and -) are where one connects the test signals to test the BIS Monitor.

Test types allowed:

Sensor check

This checks and verifies that the monitor is reporting the proper impedances that it sees from the BIS Sensor Simulator. This procedure verifies the proper functionality of the BIS monitoring system. Connect the BIS Sensor Simulator to the BIS Monitor at the patient interface cable. See Section 6.3.3 “PIC Checkout Procedure” for instructions.

The monitor should proceed to recognize that a sensor was connected and report the proper impedance values as shown below:

Electrode #	1	2	4	3
Acceptance Range in Kohms	4 - 6	8 - 17	3 - 5	2 - 4

Figure 9 - BIS Sensor Simulator individual electrode impedance range

Safety Testing: Leakage Current

Leakage current testing should be performed by a qualified Engineering Technician or authorized personnel only.

- Connect the BIS Sensor Simulator to the patient interface cable of the BIS monitor as if it was a sensor connection.
- Short the two terminals at the end of the simulator using conventional methods such as jumpers or alligator clips.
- Connect the test signal to the shorted terminals. Make sure that you are not touching the BIS Sensor Simulator beyond this point. Proceed to test instrument for Leakage current as per established facility protocols and procedure for safety testing of medical devices.



Safety Tester

Simulator Cleaning

- Wipe simulator surfaces with a wet cloth soaked in lukewarm tap water containing bleach solution of 10% by volume.
- Wipe simulator surfaces with a wet cloth of lukewarm tap water
- Dry with a clean cloth and allow to dry.

10.3 Test Sensor

Use the following procedure to make a Test Sensor:

1. Remove a new sensor from its plastic carrier sheet and place on flat surface with the adhesive facing up.

NOTE:

Be careful that gel does not leak onto hands or connector during this procedure.

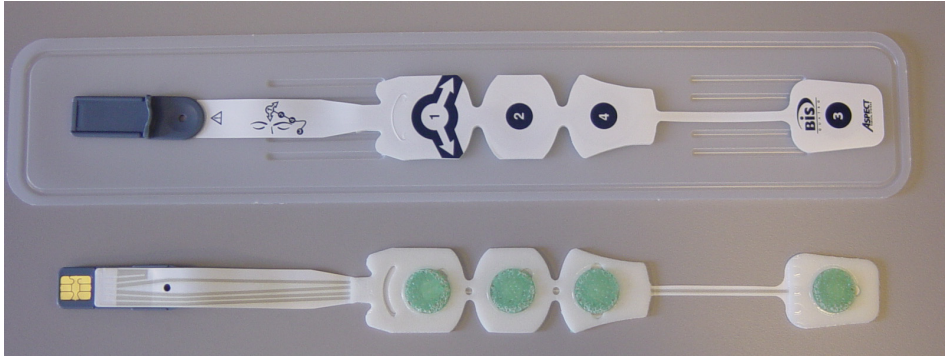


Figure 10 - BIS Sensor

2. Place the end of a small paper clip at the midpoint of electrode #2 then lay it across electrode #4. (See Figure 11.)

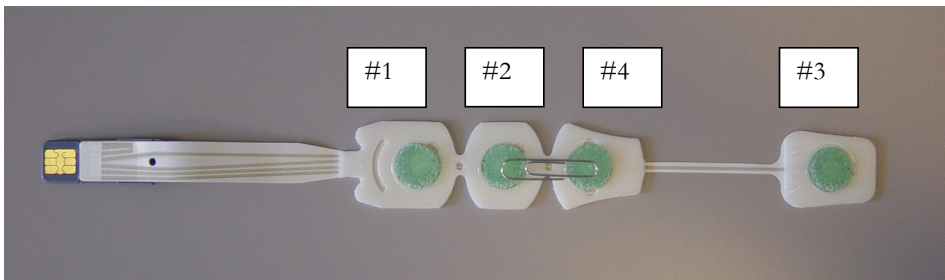


Figure 11 - Connecting electrodes #2 and #4.

3. Fold electrode #3 over onto electrode #4, pressing adhesive surfaces together and making sure the paper clip remains in place.
4. Fold electrode #1 over onto electrode #2.



Figure 12 - Connecting electrode #3 with #4, and #1 with #2.

5. Connect this Test Sensor to the PIC. All impedance tests should complete successfully, with low impedance values. Typical values using this alternative Test Sensor are less than 5 K ohms.

The following chart shows expected Test Sensor values:

Test Sensor Values		
Electrode #	Typical	Range
1	1 K ohm	1-2 K ohms
2	1 K ohm	1-3 K ohms
4	1 K ohm	1-2 K ohms
3	1 K ohm	1-2 K ohms

10.4 Safety Tester Connection with PIC

This procedure describes a method to connect a BIS VIEW Monitoring System to a safety tester. It uses a current date sensor to provide a contact point for the safety tester leads that correspond to the patient contact points of the BIS VIEW system.

1. Connect BISx cable to BIS VIEW monitor.
2. Connect PIC (Patient Interface Cable - sensor) cable to other end of BISx.
3. Verify sensor for test is of current date code. Connect sensor to PIC cable.
4. Remove gel and green pad from each sensor contact point.
5. Connect safety tester leads per tester instructions to sensor contact point pads (i.e. via alligator clips).
6. Apply power to the BIS VIEW system per safety tester instructions. Make required leakage measurements.
7. Disconnect and dispose of sensor. NOTE: DO NOT discard PIC or BISx. These are re-usable components.

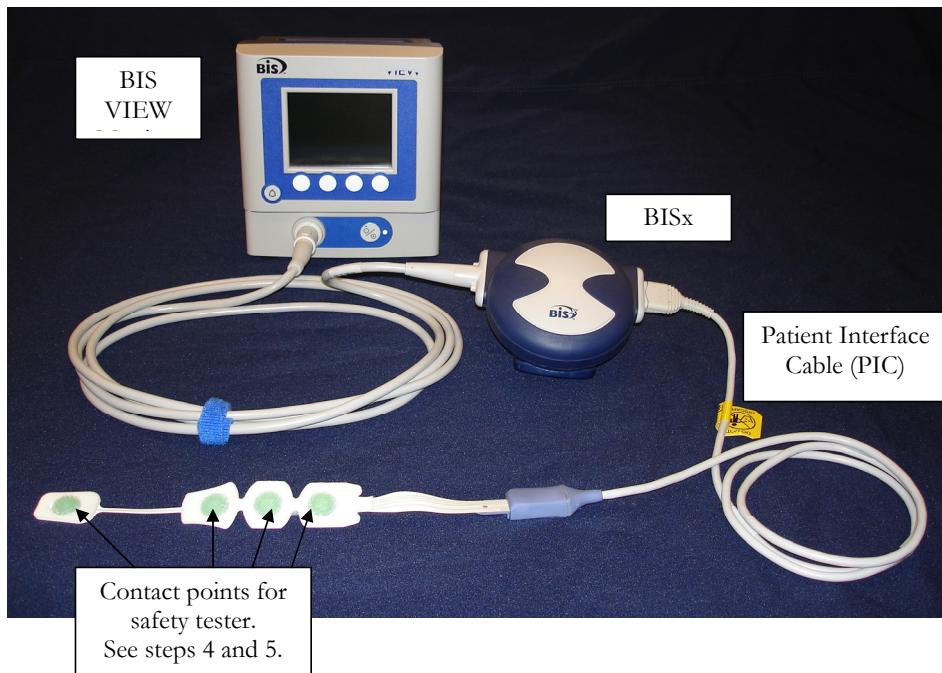
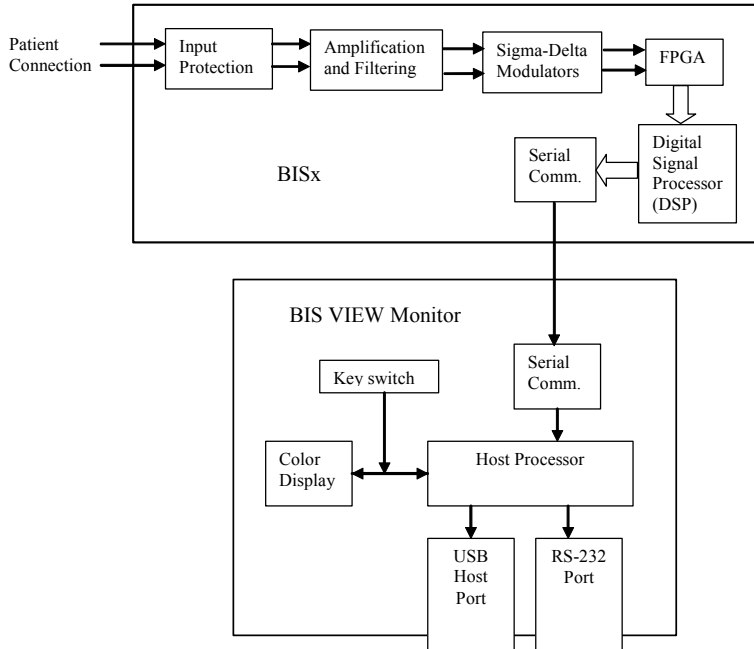


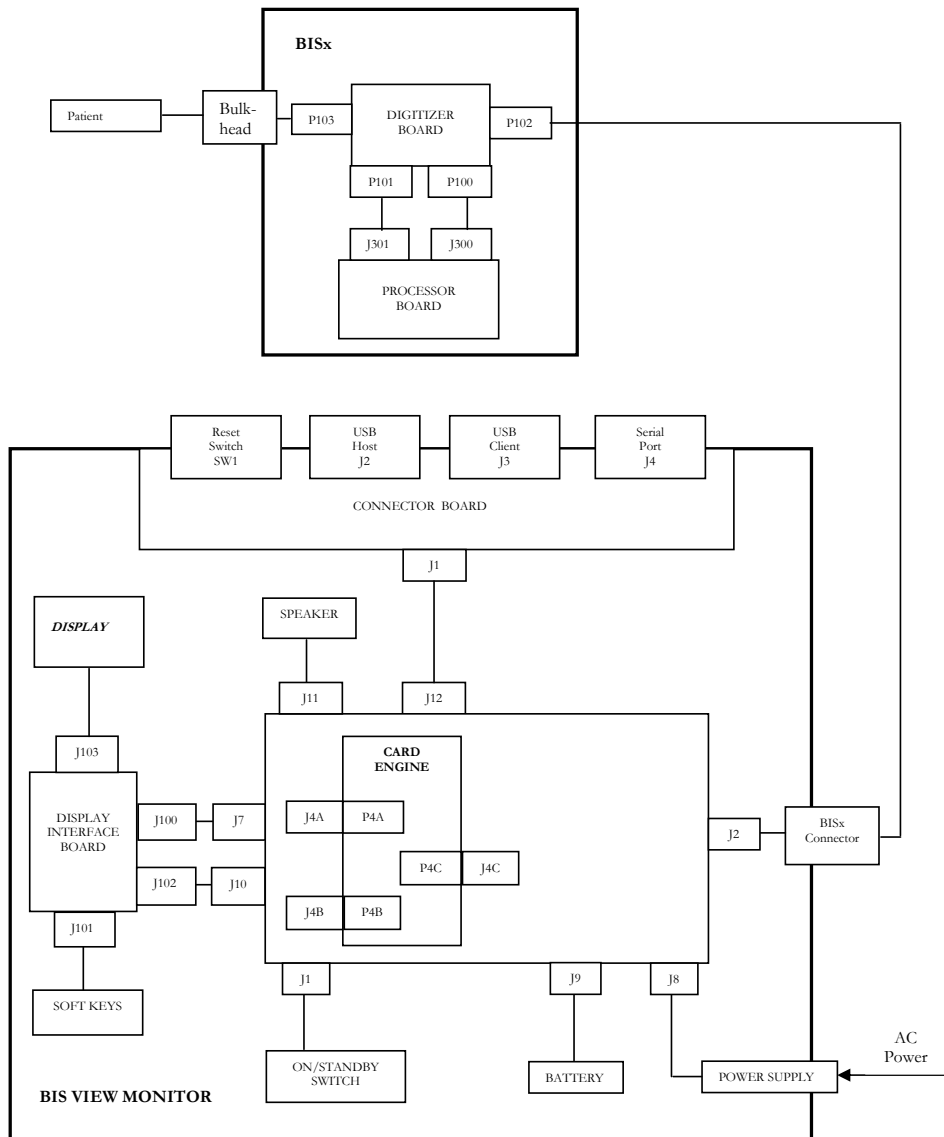
Figure 13 - Safety Tester Contact Points

II APPENDIX II

II.1 Data Flow Diagram



II.2 Block Diagram





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